

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., and ENDO  
PAR INNOVATION COMPANY, LLC

C.A. No. 23-866-JLH-LDH

*Plaintiffs,*

v.

ZYDUS PHARMACEUTICALS (USA) INC.  
and ZYDUS LIFESCIENCES LTD.

*Defendants.*

**CLAIM CONSTRUCTION BRIEF**

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**TABLE OF CONTENTS**

	<b>Page</b>
I. REPRESENTATIVE CLAIMS .....	1
A. '524 Patent.....	1
B. '587 Patent.....	1
II. AGREED-UPON CONSTRUCTIONS .....	2
III. DISPUTED CONSTRUCTIONS OF THE '524 AND '587 PATENTS.....	2
A. "0.15% (w/w)" ('587 patent, claims 1, 13, and 24).....	2
1. Par's Opening Position .....	2
2. Zydus's Answering Position.....	5
a. The '587 patent specification supports Zydus's proposed construction .....	5
b. "0.15% (w/w)" is indefinite.....	9
3. Par's Reply Position .....	11
4. Zydus's Sur-Reply Position.....	14
B. "As Measured by [Method]" ('524 patent, claims 1 and 18; '587 patent, claims 1, 13, and 24).....	16
1. Par's Opening Position .....	17
2. Zydus's Answering Position.....	18
3. Par's Reply Position .....	22
4. Zydus's Sur-Reply Position.....	23
C. "Means for Reducing the Nitrosamine Impurities" ('524 Patent, claim 1) "Means for Removing the Nitrosamine Impurities" ('524 Patent, claim 12) "Employing an Acid-Base Treatment to Remove the Nitrosamine Impurities" ('524 Patent, claims 18 and 26) .....	24
1. Par's Opening Position .....	25
2. Zydus's Answering Position.....	27
3. Par's Reply Position .....	29
4. Zydus's Sur-Reply Position.....	29
D. "an acid-base treatment" ('524 Patent, claims 1, 12, 18 and 26) .....	30
1. Par's Opening Position .....	30
a. The Court Should Afford the Term "Acid-Base Treatment" Its Plain and Ordinary Meaning to a POSA .....	30

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
b.        An “Acid-Base Treatment” Is Not Indefinite to a POSA.....	35
c.        Zydus’s Alternative Construction Is Wrong.....	36
2.        Zydus’s Answering Position.....	40
a.        The ’524 patent specification supports Zydus’s proposed construction .....	40
b.        During prosecution, the patentees disclaimed “acid-base treatments” beyond the type disclosed in the specification .....	42
c.        There is no intrinsic evidence to support Par’s proposed construction .....	43
d.        Par’s proposed construction would render the claims invalid for lack of enablement and lack of written description .....	46
e.        The dependent claims do not save Par’s proposed construction. ....	48
f.        The term “acid-base treatment” is indefinite. ....	48
3.        Par’s Reply Position .....	51
a.        Zydus’s Construction Conflicts with the Plain Meaning, the Specification, and Claims .....	51
b.        Prosecution History Disclaimer Does Not Apply .....	54
c.        Zydus’s Invalidity Arguments Are Misplaced.....	59
d.        Zydus’s Indefiniteness Argument Fails .....	59
4.        Zydus’s Sur-Reply Position.....	61
a.        There is no “plain and ordinary meaning” of this term.....	61
b.        Par disclaimed any broader scope of “acid-base treatment” .....	63
c.        Par’s proposed construction would render the claims invalid for lack of written description and enablement.....	64
d.        The claims are indefinite under Par’s construction .....	65

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>AccuScan, Inc. v. Xerox Corp.</i> , 76 F. App'x 290 (Fed. Cir. 2003) .....	43, 46, 59
<i>Active Video Networks v. Verizon Commc'ns</i> , 694 F.3d 1312 (Fed. Cir. 2012).....	28
<i>Advanced Biologics LLC v. Zimmer Biomet Spine, Inc.</i> , 2022 WL 1773672 (D. Del. June 1, 2022).....	24
<i>Ajinomoto Co. v. Int'l Trade Comm'n</i> , 932 F.3d 1342 (Fed. Cir. 2019).....	65
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003).....	4, 12
<i>Amgen Inc. v. F. Hoffmann-La Roche Ltd.</i> , 580 F.3d 1340 (Fed. Cir. 2009).....	21, 24
<i>Amgen Inc. v. Sandoz Inc.</i> , 923 F.3d 1023 (Fed. Cir. 2019).....	66
<i>Ariad Pharm., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336, 1349 (Fed. Cir. 2010).....	48
<i>Apple Computer, Inc. v. Articulate Sys., Inc.</i> , 234 F.3d 14 (Fed. Cir. 2000).....	22
<i>Aylus Networks, Inc. v. Apple Inc.</i> , 856 F.3d 1353 (Fed. Cir. 2017) .....	64
<i>Becton, Dickinson and Co. v. Tyco Healthcare Group, LP</i> , 616 F.3d 1249 (Fed. Cir. 2010).....	21
<i>Belcher Pharms., LLC v. Hospira, Inc.</i> , No. 17-cv-00775-LPS, 2019 WL 2526400 (D. Del. May 30, 2019) .....	13, 16
<i>Biagro Western Sales, Inc. v. Grow More, Inc.</i> , 423 F.3d 1296 (Fed. Cir. 2005).....	11
<i>Biogen Idec, Inc. v. GlaxoSmithKline LLC</i> , 713 F.3d 1090 (Fed. Cir. 2013).....	49, 64

<i>Bombardier Recreational Products Inc. v. Arctic Cat Inc.</i> , 785 F. App'x 858 (Fed. Cir. 2019) .....	37
<i>Cacace v. Meyer Mktg. (Macau Commercial Offshore) Co.</i> , 812 F. Supp. 2d 547 (S.D.N.Y. 2011).....	14
<i>Centocor Ortho Biotech, Inc. v. Abbott Lab's.</i> , 636 F.3d 1341 (Fed Cir. 2011).....	48
<i>Clearstream Wastewater Sys., Inc. v. Hydro -Action, Inc.</i> , 206 F.3d 1440 (Fed. Cir. 2000).....	3
<i>In re Cortright</i> , 165 F.3d 1353 (Fed. Cir. 1999).....	53
<i>Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP</i> , 838 F.3d 1224 (Fed. Cir. 2016).....	3
<i>Cydex Pharmaceuticals, Inc. v. Alembix Global Holdings SA</i> , 19-cv-956-LPS, 2020 WL 6393918 (D. Del. Nov. 2, 2020) (Stark, J.).....	39
<i>Deere &amp; Co. v. Bush Hog, LLC</i> , 703 F.3d 1349 (Fed. Cir. 2012).....	4, 39
<i>Digital Biometrics, Inc. v. Identix, Inc.</i> , 149 F.3d 1335 (Fed. Cir. 1998).....	47, 48
<i>Dow Chemical Co. v. Nova Chemicals Corp. (Canada)</i> , 809 F.3d 1223 (Fed. Cir. 2015) (Moore, J. concurring) .....	36
<i>Exxon Chem. Patents, Inc. v. Lubrizol Corp.</i> , 64 F.3d 1553 (Fed. Cir. 1995).....	22
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.</i> , 535 U.S. 722 (2002).....	46
<i>f'real Foods, LLC v. Hamilton Beach Brands, Inc.</i> , 388 F. Supp. 3d 362 (D. Del. 2019).....	65
<i>Gemtron Corp. v. Saint-Gobain Corp.</i> , 572 F.3d 1371 (Fed. Cir. 2009).....	17
<i>Genentech, Inc. v. Chiron Corp.</i> , 112 F.3d 495 (Fed.Cir.1997).....	29
<i>Grober v. Mako Products, Inc.</i> 686 F.3d 1335 (Fed. Cir. 2012).....	43, 46, 59

<i>Hand Held Prods., Inc. v. Amazon.com, Inc.</i> , No. 12-cv-00768-RGA, 2014 WL 2873902 (D. Del. June 14, 2014).....	14, 16
<i>Hilgraeve Corp. v. McAfee Assocs.</i> , 224 F.3d 1349 (Fed. Cir. 2000).....	46
<i>Hill-Rom Services, Inc. v. Stryker Corp.</i> , 755 F.3d 1367 (Fed. Cir. 2014).....	37
<i>HZNP Medicines LLC v. Actavis Labs. UT, Inc.</i> , 940 F.3d 680 (Fed. Cir. 2019).....	51
<i>Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.</i> , 381 F.3d 1111 (Fed. Cir. 2004).....	4, 11, 39
<i>Interval Licensing LLC v. AOL, Inc.</i> , 766 F.3d 1364 (Fed. Cir. 2014).....	9
<i>Intervet Inc. v. Merial Ltd.</i> , 617 F.3d 1282 (Fed. Cir. 2010).....	4
<i>K-fee System GmbH v Nespresso USA, Inc.</i> , 89 F.4th 915 (Fed. Cir. 2023) .....	58
<i>Kaken Pharm. Co. v. Iancu.</i> , 952 F.3d 1346 (Fed. Cir. 2020).....	63
<i>Kamstrup A/S v. Axioma Metering UAB</i> , 43 F.4th 1374 (Fed. Cir. 2022) .....	24
<i>Liebel-Flarsheim Co. v. Medrad, Inc.</i> , 358 F.3d 898 (Fed. Cir. 2004).....	39
<i>Maclean-Fogg Co. v. Eaton Corp.</i> , No. 07-cv-472, 2009 WL 10677521 (E.D. Tex. July 17, 2009) .....	17
<i>MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.</i> , 687 F.3d 1377 (Fed. Cir. 2012).....	65
<i>Mantissa Corp. v. First Fin. Corp.</i> , 2024 WL 607717 (Fed. Cir. Feb. 14, 2024) .....	16
<i>Mass. Inst. of Tech. v. Shire Pharms., Inc.</i> , 839 F.3d 1111 (Fed. Cir. 2016).....	55, 59
<i>MBO Labs., Inc. v. Becton, Dickinson &amp; Co.</i> , 474 F.3d 1323 (Fed. Cir. 2007).....	12

<i>Mentor H/S, Inc. v. Medical Device Alliance, Inc.</i> , 244 F.3d 1365 (Fed. Cir. 2001).....	26
<i>Molins PLC v. Quigg</i> , 837 F.2d 1064 (Fed. Cir. 1988).....	23
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 572 U.S. 898 (2014).....	<i>passim</i>
<i>Phillips v. A WH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc).....	<i>passim</i>
<i>Purdue Pharma v. Epic Pharma</i> , 811 F.3d 1345 (Fed. Cir. 2016).....	21
<i>PureChoice, Inc. v. Honeywell Int’l, Inc.</i> , 333 F. App’x 544 (Fed. Cir. 2009) .....	52
<i>Retractable Techs., Inc. v. Becton, Dickinson &amp; Co.</i> , 653 F.3d 1296 (Fed. Cir. 2011).....	15
<i>Rexnord Corp. v. Laitram Corp.</i> , 274 F.3d 1336 (Fed. Cir. 2001).....	10
<i>Sequoia Tech., LLC v. Dell, Inc.</i> , 66 F.4th 1317 (Fed. Cir. 2023) .....	62
<i>SmithKline Beecham Corp. v. Apotex Corp.</i> , 439 F.3d 1312 (Fed. Cir. 2006).....	17
<i>Sonix Tech. Co. v. Publ’ns Int’l, Ltd.</i> , 844 F.3d 1370 (Fed. Cir. 2017).....	36
<i>Springs Window Fashions LP v. Novo Indus., L.P.</i> , 323 F.3d 989 (Fed. Cir. 2003).....	<i>passim</i>
<i>Summit 6, LLC v. Samsung Elecs. Co.</i> , 802 F.3d 1283 (Fed. Cir. 2015).....	26
<i>SunRace Roots Enter. Co., Ltd. v. SRAM Corp.</i> , 336 F.3d 1298 (Fed. Cir. 2003).....	39, 41
<i>Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.</i> , 743 F.3d 1359 (Fed. Cir. 2014).....	60
<i>Tech. Props. Ltd. LLC v. Huawei Techs. Co.</i> , 849 F.3d 1349 (Fed. Cir. 2017) .....	64

<i>Teleflex, Inc. v. Ficosa North Am. Corp.</i> , 299 F.3d 1313 (Fed. Cir. 2002).....	37
<i>Tempo Lighting, Inc. v. Tivoli, LLC</i> , 742 F.3d 973 (Fed. Cir. 2014).....	11, 31
<i>Teva Pharms. USA, Inc. v. Sandoz, Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015).....	36
<i>Texas Instruments Inc. v. U.S. Int’l Trade Comm’n</i> , 988 F.2d 1165 (Fed. Cir. 1993).....	21
<i>In re Thorpe</i> , 777 F.2d 695 (Fed. Cir. 1985).....	17, 19, 21
<i>V-Formation, Inc. v. Benetton Grp. SpA</i> , 401 F.3d 1307 (Fed. Cir. 2005).....	14
<i>Verizon Servs. Corp. v. Vonage Holdings Corp.</i> , 503 F.3d 1295 (Fed. Cir. 2007).....	45, 53
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996).....	45
<i>Wellman, Inc. v. Eastman Chemical</i> , 642 F.3d 1355 (Fed. Cir. 2011).....	36
<i>Wyeth &amp; Cordis Corp. v. Abbott Laby’s</i> , 720 F.3d 1380 (Fed. Cir. 2013).....	47
<i>XMTT, Inc. v. Intel Corp.</i> , 657 F. Supp. 3d 591 (D. Del. 2023).....	66

## **Statutes**

35 U.S.C. § 282(a) .....	3
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## **Other Authorities**

MPEP 608.01(m) .....	56
MPEP 2113 .....	19, 20, 23

## I. REPRESENTATIVE CLAIMS

### A. '524 Patent

1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:

- (a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and
- (b) *means for reducing the nitrosamine impurities* to less than 50 ppm per tablet *as measured by LC-ESI-HRMS Method*;<sup>1</sup>

wherein the means comprises an *acid-base treatment*.

12. A method of making varenicline tartrate comprising less than 50 ppm of nitrosamine impurities, the method comprising:

- (a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and
- (b) *means for removing the nitrosamine impurities* in the varenicline tartrate to less than 50 ppm;

wherein the means comprises an *acid-base treatment*.

18. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities *as measured by LC-ESI-HRMS Method* the method comprising:

- (a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and
- (b) *employing an acid-base treatment to remove the nitrosamine impurities*.

26. A method of making varenicline tartrate comprising less than 50 ppm of nitrosamine impurities, the method comprising:

- (a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and
- (b) *employing an acid-base treatment to remove the nitrosamine impurities*.

### B. '587 Patent

1. A pharmaceutical composition in the form of a tablet, comprising varenicline tartrate, wherein the tablet comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity *as measured by LC-ESI-HRMS (U.S. FDA Method)* and less than **0.15% (w/w)** of diamide (Bis (7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]-benzazepine)-amide) impurity *as measured by RS Method-II*.

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<sup>1</sup> Disputed claim terms are italicized and bolded.

**13.** A pharmaceutical composition in the form of a tablet, comprising between about 0.85 mg and about 1.7 mg varenicline tartrate, wherein the varenicline tartrate comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity *as measured by LC-ESI-HRMS (U.S. FDA Method)* and less than **0.15% (w/w)** of varenicline N-glucoside impurity *as measured by RS Method-III*.

**24.** A pharmaceutical composition in the form of a tablet, comprising between about 0.5 mg and about 1 mg varenicline free base and tartaric acid as a counterion to the varenicline free base, wherein the tablet comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity *as measured by LC-ESI-HRMS (U.S. FDA Method)* and less than **0.15% (w/w)** diamide (Bis (7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]-benzazepine)-amide) impurity *as measured by RS Method-II*.

## II. AGREED-UPON CONSTRUCTIONS

None.

## III. DISPUTED CONSTRUCTIONS OF THE '524 AND '587 PATENTS

### A. “0.15% (w/w)” ('587 patent, claims 1, 13, and 24)

Par's Proposed Construction	Zydus's Proposed Construction
Not indefinite; Plain and ordinary meaning	Indefinite
To the extent the court requires a construction, “0.15% (weight of one substance divided by weight of another substance)” each of the claims identified by Zydus specify what the substances are.	To the extent the court requires a construction, “0.15% (w/w) of [impurity]/Varenicline Tartrate Maltodextrin premix (1:10)”

#### 1. Par's Opening Position

The phrase “(w/w)” means “weight by weight,” a common term in chemistry, which means just what it says—dividing the measured weight of one substance by the measured weight of another. The substances comprising the numerator and denominator of the fraction are defined in the claims. That is the ordinary meaning.

Zydus makes the broad-brush assertion that all claims using this common term are indefinite or in the alternative that the denominator must always be varenicline tartrate maltodextrin premix, even where the claims expressly say otherwise. It is Zydus's burden to

establish invalidity, and a challenger must prove indefiniteness by clear and convincing evidence. *See* 35 U.S.C. § 282(a); *Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP*, 838 F.3d 1224, 1228 (Fed. Cir. 2016) (“Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence.”). The standard is that “[a] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Where, as here, the claim term at issue is in common use and the claims themselves define how to perform the calculation, the claims are definite.

Based on its invalidity contentions, Zydus appears to be taking the position that a POSA would not understand whether the “weight-weight percentage is in the tablets, in the varenicline tartrate, or in the varenicline tartrate maltodextrin premix API.” JA125. The argument has no merit because the claims expressly define the relevant denominator. Claims 1 and 24 state “wherein *the tablet* comprises . . . less than 0.15% (w/w) of [diamide impurity] as measured by RS Method-II.” JA1-60 (the “’587 patent”), cls. 1, 24 (emphasis added). Because the “tablet” must have less than 0.15% of the diamide impurity, these claims define the % w/w calculation as a percentage based on the weight of the tablet. Claim 13 claims a tablet “wherein *the varenicline tartrate* comprises less than . . . 0.15% (w/w) of varenicline N-glucoside impurity as measured by RS Method-III.” *Id.*, cl. 13 (emphasis added). Claim 13 therefore states that its % w/w calculation is determined using the weight of the varenicline tartrate in the tablet. *See Clearstream Wastewater Sys., Inc. v. Hydro -Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000) (“Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims.”). Each claim

therefore specifies the relevant numerator—the weight of the specified impurity—and the relevant denominator—the weight of the tablet or varenicline tartrate—for the % w/w calculation. The dependent claims further confirm this understanding. *See* ’587 patent, cl. 9 (“less than 0.15% (w/w) . . . impurity *per tablet*”), cl. 15 (“the *varenicline tartrate* further comprises less than 0.15% (w/w)” of specified impurity) (emphasis added). There is no ambiguity.

Zydus’s alternative construction also fails. The claims do not state that a “varenicline tartrate maltodextrin premix” comprises less than 0.15 % (w/w) of an impurity. Indeed, there is not a single claim—independent or dependent—which limits the claimed tablets to those manufactured using a maltodextrin premix. *See* ’587 patent, cls. 1, 13, 24. The specification defines the term “premix,” but the claims do not employ the term. *Id.*, 6:1-4. And the specification refers to a maltodextrin premix as merely one embodiment of the claimed invention. *See id.*, 24:8-27 (“[i]n one embodiment, the Varenicline Tartrate Maltodextrin Premix (1:10)”), 3:3-46, 33:8-24.<sup>2</sup> Zydus’s construction improperly imports “limitations from the specification into the claims.” *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1354 (Fed. Cir. 2012); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (“[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect.”). “Construing the claims in light of the specification does not [] imply that limitations discussed in the specification may be read into the claims.” *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010); *Amgen Inc. v.*

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<sup>2</sup> Indeed, Par procured a separate patent—U.S. Patent No. 11,602,537—in the same patent family with claims directed specifically to a pharmaceutical composition “wherein the varenicline tartrate is dispersed in a maltodextrin matrix.” JA127 (the “’537 patent”), cl. 1. When Par wanted to limit claims to the use of a maltodextrin matrix, Par did so explicitly.

*Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1325 (Fed. Cir. 2003) (“The danger of improperly importing a limitation is even greater when the purported limitation is based upon a term not appearing in the claim.”).

Moreover, Zydus’s construction is inconsistent with the specification. Particularly, the specification provides a method, including a calculation, for detecting and quantifying impurities in a varenicline tartrate maltodextrin premix. That method, RS Method-III, calculates the % (w/w) of an impurity using the weight of the varenicline tartrate, ***not the weight of the maltodextrin premix***. JA185 (“Dodds Decl.”) at JA201-203 ¶¶ 36-41; ’587 patent, 55:29-56:53. Thus, even the example in the specification reporting impurities in the maltodextrin premix uses the varenicline tartrate as the denominator, not the premix. Indeed, none of the calculations provided in the patent report the % w/w of an impurity based on the weight of the maltodextrin premix. ’587 patent, 50:5-67:20 (Example 8). Thus, Zydus’s “alternative” construction is contradicted by the plain language of the claims and the specification.

## 2. Zydus’s Answering Position

### a. The ’587 patent specification supports Zydus’s proposed construction

A POSA<sup>3</sup> reading the specification and prosecution history would understand that the denominator of “0.15% (w/w) of [diamide impurity or varenicline N-glucoside impurity]” is Varenicline Tartrate Maltodextrin premix (1:10).

The ’587 patent discloses a process for making a “varenicline active pharmaceutical ingredient (‘API’) that has an acceptable level of nitrosamine impurities.” ’587 patent, 1:55-57.

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<sup>3</sup> For purposes of claim construction briefing, Zydus relies on the definition of a POSA set forth in the Declaration of Steven W. Baertschi, Ph.D., in Support of Zydus’s Claim Construction JA344(“Baertschi Declaration”), JA355, ¶31.

That “API” is a varenicline tartrate maltodextrin premix, which contains varenicline tartrate and maltodextrin in a ratio of 1:10. The specification repeatedly refers to varenicline tartrate maltodextrin premix as the “API.” *See, e.g.,* ’587 patent, 23:10-13 (“[t]hree nitrosamine impurities could have formed during the manufacturing process of *Varenicline Tartrate Maltodextrin premix (1:10) API*”); 34-36 (“six process Related/Degradation impurities are controlled in *varenicline tartrate maltodextrin premix API* with the limit of NMT 0.15% w/w”) (emphasis added to both). The first process disclosed in the “Summary” of the specification is a process for making varenicline tartrate maltodextrin premix (1:10) API. *Id.* at 2:6-42 (describing a process that “results in the 7,8,9,10-tetrahydro-6,10-methano-6h-pyrazino[2,3-h][3] benzazepine, (2r,3r)-2,3-dihydroxy butanedioate. maltodextrin premix (1:10) being substantially free from nitrosamine impurities” (in which, “7,8,9,10-tetrahydro-6,10-methano-6h-pyrazino[2,3-h][3] benzazepine” is varenicline; “(2r,3r)-2,3-dihydroxy butanedioate” is tartrate)). In the “Detailed Description” section of the specification, under the heading “Process for Making Varenicline,” the patent states “[g]enerally, there are four stages in the synthetic procedure of varenicline tartrate that results in active pharmaceutical ingredient (‘API’) that is substantially free of impurities.” *Id.* at 7:15-20. The four-stage process described there results in varenicline tartrate maltodextrin premix (1:10). *Id.* at 7:21-33.

The disputed “0.15% (w/w)” term appears in claims 1, 13, and 24 as a limit on certain impurities—the “diamide” and “varenicline N-glucoside” impurities—that are discussed in the specification as impurities in the maltodextrin premix API. The ’587 patent states that the diamide and varenicline N-glucoside impurities are “controlled in varenicline tartrate maltodextrin premix API with the limit of NMT 0.15% w/w.” *Id.* at 23:34-36; *see also id.* at Table 5 at cols. 29-32 and Table 14 at 51:27-43 (disclosing diamide and varenicline N-glucoside

impurities as among the six impurities related to varenicline tartrate maltodextrin premix API). Indeed, the '587 patent expressly states that the varenicline N-glucoside impurity is formed “due to reaction of degradation products of Maltodextrin with Varenicline,” meaning that these impurities do not exist prior to the formation of the premix. *Id.* at 50:14-18. Given that the diamide and varenicline N-glucoside impurities are identified in the specification as potential impurities in the maltodextrin premix API, and not in varenicline tartrate or a varenicline tablet, a POSA would understand that the claimed “0.15% (w/w)” is a measurement of those impurities in the maltodextrin premix API. *See, e.g.,* '587 patent, 23:10-13; 34-36.

The '587 patent states that diamide and varenicline N-glucoside impurities “are controlled with the limit of not more than (NMT) 0.15% *as per ICH Q3A*.” *See* '587 patent, 23:32-33 (emphasis added). ICH Q3A is scientific guidance adopted by FDA and provides for the content and qualification of impurities in new drug substances, or APIs. *See* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q3ar-impurities-new-drug-substances>. ICH Q3A sets a 0.15% w/w threshold for impurities in an API, and not a final dosage form (i.e. tablet). JA621 (“ICH Q3A”) at JA633, 8. Although ICH Q3A could, in the abstract, apply equally to a varenicline tartrate API or a maltodextrin premix API, as explained above, the '587 patent consistently identifies “Varenicline Tartrate Maltodextrin premix (1:10)” as the API in which the diamide and varenicline N-glucoside impurities are measured.

The specific methods recited in the claims for measuring the amount of the diamide and N-glucoside impurities further support Zydus’s construction. The '587 patent explains that those methods—RS Method-II and RS Method-III—were developed for analyzing either varenicline base (from Stage III of the synthetic process for varenicline tartrate maltodextrin premix API) or

the varenicline tartrate maltodextrin premix itself, not a tablet or a varenicline tartrate API. ’587 patent, Example 8, 50:5-59:27; *see, e.g.*, 56:55-57 (“RS Method-I, RS Method-II, and RS Method-III for Analyzing the Varenicline Tartrate Maltodextrin Premix API”); 51:43-45 (disclosing that “Diamide Impurity has been controlled with 0.15% w/w Varenicline Tartrate Maltodextrin premix (1:10) by using Method-II”); and 55:33-35 (disclosing that “[RS Method-III] is used as a control of . . . Varenicline-N-glucoside impurity in varenicline tartrate maltodextrin premix (1:10)”).

Par argues that because the claims do not recite 0.15% (w/w) of [impurity] per varenicline tartrate maltodextrin premix (1:10), Zydus improperly imports limitations from the specification into the claims. *See supra*, 4-5. However, a claim term must be construed in light of the patent specification in which it resides. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (“We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.”) As discussed above, the specification makes clear that the patentees used the term “0.15% (w/w)” based on the ICH Q3A limit of 0.15% (w/w) in a drug substance and the ’587 patent discloses the varenicline tartrate maltodextrin premix (1:10) API as the relevant drug substance for controlling the diamide and glucoside impurities. Moreover, reading claims 1 and 24 to permit 0.15% (w/w) of a tablet (which includes API and other ingredients, and thus weighs more than the API itself) would allow substantially higher levels of impurity than the limits prescribed in ICH Q3A.

Par further asserts that Zydus’s construction is inconsistent with the specification because RS Method-III (the method recited in claim 13 for measuring the N-glucoside impurity) calculates the % (w/w) of an impurity using the weight of the varenicline tartrate, not the weight of the

maltodextrin premix. *See supra*, 5. But, as Par acknowledges, the equation in question appears in the section titled “Related Substance Method III for Analyzing Varenicline Tartrate Maltodextrin Premix (1:10) (Stage 4) (RS Method III).” ’587 patent, 55: 29-31. Moreover, a POSA would know how to calculate the amount of impurities using the weight of the varenicline tartrate maltodextrin premix (1:10) API as the denominator. A POSA would also understand that the sample preparation in the same section requires dissolving “550 mg of premix in 50 ml.” ’587 patent, 56:29. In any event, the specification nowhere discloses measuring the relevant impurities as a percentage of a tablet, as Par would read claims 1 and 24.

For at least these reasons, the Court should adopt Zydus’s construction of “0.15% (w/w)” to mean “0.15% (w/w) of [diamide impurity or varenicline N-glucoside impurity]/Varenicline Tartrate Maltodextrin premix (1:10)” as supported by the intrinsic evidence.

**b. “0.15% (w/w)” is indefinite**

Should the Court not adopt Zydus’s proposed construction, claims 1, 13, and 24 are indefinite because a POSA would not be able to determine the appropriate denominator of “0.15% (w/w).”

A patent claim is invalid for indefiniteness if the claim, “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). “The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). A POSA reading the specification would not, with reasonable certainty, be able to ascertain the meaning of the claim limitations reciting “less than 0.15% (w/w)” in claims 1, 13, and 24, at least because a POSA would not understand whether the weight-weight percentage is relative to tablets, varenicline

tartrate, or varenicline tartrate maltodextrin premix API. *See Nautilus*, 572 U.S. at 910.

Par argues that “0.15% (w/w)” should be read as a measurement of impurities based on the weight of varenicline tartrate or a varenicline tartrate tablet depending on the claim in which the term appears. But the specification nowhere discloses any percentage (w/w) of diamide impurity in a tablet or the use of RS Method-II to measure the % (w/w) of diamide impurity in a tablet. *See* ’587 patent, 50:5-68:50. Likewise, the specification nowhere discloses any percentage (w/w) of varenicline N-glucoside impurity in varenicline tartrate or the use of RS Method-III to measure the % (w/w) of varenicline N-glucoside impurity in varenicline tartrate. *Id.* Moreover, the specification provides no basis for evaluating these two impurities using different denominators, especially where the 0.15% w/w limit in the claims is based on the limit set forth in ICH Q3A, which is directed to controlling impurities in an API, and not a tablet. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) (holding that a “claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent”).

Absent a uniform construction of “0.15% (w/w)” as a percentage of Varenicline Tartrate Maltodextrin premix across all of the claims, different claims would permit significantly different amounts of impurities. For example, 0.15% (w/w) using the tablet as a denominator would permit a much higher level of impurities—because the tablet contains other components and therefore weighs more—than using the maltodextrin premix. The level of impurities permitted by a limit of 0.15% (w/w) of the tablet could be well beyond the 0.15% (w/w) impurity threshold specified in ICH Q3A for the API. Accordingly, beyond the specification’s disclosure that “0.15% (w/w)” is a measurement of the amount of impurities in the varenicline maltodextrin premix, a POSA would not be able to ascertain the scope of the claims with reasonable certainty.

### 3. Par's Reply Position

This dispute boils down to a simple question: what is the proper denominator for each “w/w” limitation in the ’587 claims? Zydus insists in all cases that the denominator is the amount of maltodextrin premix, even though no claims mention a premix, and even though each claim expressly states that the denominator is either the tablet or the varenicline tartrate.

“It is elementary that claim construction begins with, and remains focused on, the language of the claims.” *Biagro Western Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005). Zydus ignores the claim language, focusing instead on how a POSA would “read[] the specification and prosecution history.” *Supra*, III.A.2.a. But Zydus cannot dispute that it is improper to import limitations from the specification into the claims. *See supra*, III.A.1; *Innova/Pure Water*, 381 F.3d at 1117 (“[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect.”). That portions of the specification refer to varenicline tartrate maltodextrin premix does not mean ***all of the asserted claims*** are so limited.

Par’s construction properly begins with the claim language. *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (“In claim construction, this court gives primacy to the language of the claims....”). Claims 1 and 24 recite that the “tablet” comprises certain impurity percentages. *See supra*, III.A.1; ’587 patent, cls. 1, 24. Claim 13 states that the “varenicline tartrate” comprises certain impurity percentages. *See supra*, III.A.1; ’587 patent, cl. 13. The dependent claims similarly confirm that the impurities are calculated based on the weight of the tablet or varenicline tartrate. *See* ’587 patent, cl. 9 (“less than 0.15% (w/w) . . . impurity ***per tablet***”), cl. 15 (“the ***varenicline tartrate*** further comprises less than 0.15% (w/w)” of specified impurity) (emphasis added). None of the asserted claims state that the denominator is maltodextrin premix. The clear and unambiguous language of the claims must control. *See*

*MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) (“[W]e cannot endorse a construction analysis that does not identify a textual reference in the actual language of the claim with which to associate a proffered claim construction”) (cleaned up).

Zydus nevertheless argues that, based on the specification, the claimed impurity requirements should be read as using varenicline tartrate maltodextrin premix (1:10) as denominator. *Supra*, to III.A.2.a. Zydus asks this Court to construe tablet claims—which make no mention of any maltodextrin premix—as requiring the use of a maltodextrin premix in their manufacture. But there is simply no textual hook in the claim to importing such a limitation from the specification. *See Amgen*, 314 F.3d at 1325 (“The danger of improperly importing a limitation is even greater when the purported limitation is based upon a term not appearing in the claim.”).

Indeed, the prosecution history, which Zydus cites without any particular citation, is consistent with Par’s construction. Claims 1 and 24 were amended during prosecution to specify that the “tablet” comprises less than 0.15% (w/w) of diamide impurity. *See* JA518-526. Claim 13 was amended to specify that the “varenicline tartrate” comprises less than 0.15% (w/w) of varenicline N-glucoside impurity. *Id.* Par amended the claims to overcome a “Wei” reference. For claims 1 and 24, Par argued that “Wei does not teach or disclose a varenicline tartrate tablet that contains less than 0.15% (w/w) of diamide impurity ***in the tablet***.” JA528 at 12 (emphasis added). Par also argued that Wei did not teach the “less than 0.15% (w/w) of varenicline N-glucoside impurity ***in the varenicline tartrate API***.” JA529 at 13 (emphasis added). Thus, Par argued to the Examiner that the impurity percentages in the claims were based on the weight of the overall tablet or the weight of the varenicline tartrate API, ***never the premix***.

Zydus misleadingly quotes the specification (*supra*, III.A.2.a), suggesting that it states that the N-glucoside impurity is only formed due to the reaction of maltodextrin with varenicline. The specification actually states that the impurity “*could* form” due to this reaction, ’587 patent at 50:14-18, but it never says that these impurities *only* occur in a tablet using maltodextrin premix. More importantly, Zydus does not dispute that the w/w calculations actually reported in the patent for the N-glucoside impurity were calculated using varenicline tartrate, not maltodextrin premix, as the denominator. In Zydus’s words: “RS Method-III . . . calculates the % (w/w) of an impurity using the weight of the varenicline tartrate, not the weight of the maltodextrin premix.” *Supra*, III.A.2.a; *see also* Dodds Decl., JA201-203 at ¶¶ 36-41; ’587 patent, 55:29-56:53.

Zydus misreads the specification in other ways. It observes that there is a section title that includes the phrase “[m]altodextrin [p]remix,” (*supra*, III.A.2.a), but that is hardly a substitute for reading the actual text of the patent. In the examples describing the manufacture of a maltodextrin premix, the w/w measurement is based on “the weight of the varenicline tartrate,” *not the premix*. Dodds Decl., JA203 at ¶ 41. Similarly, Zydus also cites to specification passages referring to the term “varenicline tartrate maltodextrin premix API.” *Supra*, III.A.2.a. But the claims do not use the term “maltodextrin premix API” or even “API.” *See* ’587 patent, cls. 1, 13, 24.<sup>4</sup> These portions of the specification have no relevance to the construction of the claims, which are self-defining. *See Belcher Pharms., LLC v. Hospira, Inc.*, No. 17-cv-00775-LPS, 2019 WL 2526400, at \*2 (D. Del. May 30, 2019) (“Plaintiff is correct

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<sup>4</sup> Indeed, Par has obtained a separate patent where claims are directed to varenicline in a “maltodextrin matrix.” ’537 patent, cl. 1.

that the specification repeatedly refers to the ‘in-process’ pH. But the *claim* does not use this term....”).

Zydus also relies on the ICH Q3A guidelines, which are extrinsic evidence, not referenced in the claims, and “apply equally to a varenicline tartrate API or a maltodextrin premix API” as Zydus admits. *Supra*, III.A.2.a. Thus, even if appropriate to consider, these guidelines do not establish that the claimed 0.15 % (w/w) must refer to a premix.

For the same reasons, the Court should reject Zydus’s indefiniteness position. The claim language is clear and unambiguous. Even though indefiniteness is judged from the perspective of a POSA, Zydus proffers no expert opinion. Its reliance on attorney argument is insufficient to carry its burden. *See Hand Held Prods., Inc. v. Amazon.com, Inc.*, No. 12-cv-00768-RGA, 2014 WL 2873902, at \*16 (D. Del. June 14, 2014); *Cacace v. Meyer Mktg. (Macau Commercial Offshore) Co.*, 812 F. Supp. 2d 547, 560 (S.D.N.Y. 2011) (both cases rejecting indefiniteness challenge based on attorney argument alone).

#### 4. Zydus’s Sur-Reply Position

Par asserts “[t]he clear and unambiguous language of the claims must control.” *Supra*, 11. The claim language is not so clear. The claims require using ***RS Method-II*** and ***RS Method-III***, which were developed specifically for analyzing impurities in varenicline base or the varenicline tartrate maltodextrin premix. *Supra*, 7-8. The claims further set “**0.15% w/w**” as the limit for impurities, which the specification makes clear comes from the ICH Q3A guidance for impurities in an API, not in a final product (tablet).

ICH Q3A guidelines—contrary to Par’s assertion—are intrinsic evidence because they are cited in the patent. *Supra*, 14; *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (“‘prior art cited in a patent...constitutes intrinsic evidence’ ... this court

interpreted the term based on its usage in the prior art that was cited in the patent.”) (internal citations omitted). By stating that the impurities “are controlled with the limit of not more than (NMT) 0.15% as per *ICH Q3A*,” the applicants evinced their intent to adopt the meaning in that guidance. *Id.* Par does not argue that ICH Q3A guidelines apply to a tablet. *Supra*, 14. Indeed, setting a limit of NMT 0.15% w/w *per tablet* would allow the drug product to contain far more impurities than the regulatory threshold set forth in ICH Q3A.<sup>5</sup>

The specification makes clear that the relevant API is varenicline tartrate maltodextrin premix because that is the only API disclosed in the “Impurities” section. ’587 patent, 23:8-33:41. Table 5, which identifies “Possible Varenicline Impurities in Varenicline base (Stage 3) and *Varenicline Tartrate Maltodextrin premix API* (Stage 4)” states that diamide and varenicline N-glucoside impurities are “controlled in premix API with a limit NMT 0.15% w/w.” *Id.* (emphasis added.) The specification does not disclose controlling these impurities in a tablet or varenicline tartrate. *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (“the claim construction process entails more than viewing the claim language in isolation” and requires “tether[ing] the claims to what the specifications indicate[d] the inventor actually invented.”).

Par mischaracterizes Zydus’s position on the N-glucoside impurity. *Supra*, 13, *compare to 6-7*. Zydus is not arguing that the N-glucoside impurity can only form in a tablet using maltodextrin. *Id.* The point is that there is no reason to control this impurity in varenicline tartrate because it does not exist outside of the varenicline tartrate maltodextrin premix. *Supra*, 6-7. Par identified no intrinsic evidence to the contrary.

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<sup>5</sup> For example, for a 200 mg tablet containing 1 mg of an API, 0.15% w/w of impurity in the tablet would be 0.3 mg of that impurity, or 30% w/w of impurity in the API, *two hundred times greater* than the threshold set in the ICH Q3A.

Par’s reliance on *Belcher Pharms.* is misplaced. *Supra*, 13-14. The *Belcher* court found that the claim was directed to a final product, and therefore rejected a construction requiring an “in-process pH” for an intermediate not in the final product. 2019 WL 2526400, at \*2. Here, however, varenicline tartrate maltodextrin premix is not an intermediate; it is the API in which the impurities are controlled in the claimed final product.

Citing *Hand Held*, Par requests the Court reject Zydus’s indefiniteness position because “Zydus proffers no expert opinion.” *Supra*, 14. Par misreads the case law. In *Hand Held*, the Court stated that for determining indefiniteness, “[t]he Federal Circuit has ‘noted that typically expert testimony will be necessary in cases involving *complex technology*.’ Although the *Elcommerce.com* court stated ‘[w]e do not of course hold that expert testimony will always be needed for every situation. . .’” 2014 WL 2873902, at \*5 (emphasis added). Here, according to Par, “what is the proper denominator for each ‘w/w’ limitation in the ’587 claims” is “a simple question.” *Supra*, 11.

Zydus does not rely on attorney argument or extrinsic evidence for this point; it relies on the intrinsic evidence from which the Court can determine that the term is indefinite. *Mantissa Corp. v. First Fin. Corp.*, 2024 WL 607717, at \*2 (Fed. Cir. Feb. 14, 2024) (it is unnecessary to rely on expert testimony to conclude the claims were indefinite).

**B. “As Measured by [Method]” (’524 patent, claims 1 and 18; ’587 patent, claims 1, 13, and 24)**

<b>Par’s Proposed Construction</b>	<b>Zydus’s Proposed Construction</b>
Not product-by-process claims.  The claims do not require the accused infringer to use the methods recited in the claims to measure the impurity.	Should be construed similar to the “product-by-process claims”. <i>See</i> MPEP 2113 (“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

	If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” <i>In re Thorpe</i> , 777 F.2d 695, 698 (Fed. Cir. 1985)) (citations omitted).
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### 1. Par’s Opening Position

Zydus contends that the “as measured by [method]” limitations in the ’524 and ’587 patents should be “construed similar to the ‘product-by-process claims.’” It is unclear what Zydus means by “similar to” or what construction Zydus asks the Court to adopt. The claims are not product-by-process claims. “A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made.” *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (citations omitted).

The ’587 patent claims are “product” claims covering a tablet with certain characteristics. *See* ’587 patent, cls. 1, 13, 24. One of those characteristics is that the tablets contain certain levels of impurities if measured using specific methods—LC-ESI-HRMS, RS Method-II, RS Method-III. *Id.* The “as measured by” limitations do not define any process by which tablets are made; they recite properties of the claimed tablets using certain measurement techniques. *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009) (“Defining a structural component by its functional as well as its physical characteristics is different from defining a structure solely by the process by which it is made.”).

The same is true for the ’524 patent. The ’524 patent claims are methods of manufacturing tablets, not product-by-process claims. JA61-118 (the “’524 patent”), cls. 1, 18 (a “method of making a varenicline tartrate tablet . . .”). The ’524 claims are not product claims and therefore are obviously not product-by-process claims. *See Maclean-Fogg Co. v. Eaton*

*Corp.*, No. 07-cv-472, 2009 WL 10677521, at \*24 (E.D. Tex. July 17, 2009) (“Unlike the product and product-by-process claims previously discussed herein, this claim discloses a method for cold forming a valve lifter body.”). The ’524 patent’s method claims cover the use of an acid-base treatment in a method of manufacturing a tablet. ’524 patent, cls. 1, 18. There is no reason to construe the claim as a product-by-process claim or “similar to” a product-by-process claim.

## 2. Zydus’s Answering Position

The disputed claim terms “as measured by [method]” are found in the following representative claim limitations:

- means for reducing the nitrosamine impurities to less than 50 ppm per tablet *as measured by LC-ESI-HRMS Method*, ’524 patent, claim 1;
- the tablet comprises less than 50 ppm of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity *as measured by LC-ESI-HRMS (U.S. FDA Method)* and less than 0.15% (w/w) of diamide (Bis (7,8,9,10-tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]-benzazepine)-amide) impurity *as measured by RS Method-II*, ’587 patent, claim 1.

These claim limitations recite specific methods to measure the respective claimed impurities. However, the ’587 patent discloses that the impurities can be measured using other methods, including “HPLC, LCMS, column chromatography, paper chromatography, thin-layer chromatography, liquid chromatography, affinity chromatography, ion exchange chromatography, size-exclusion chromatography, reversed-phase chromatography, titration, NMR, or LC-ESI-HRMS.” *See, e.g.*, ’587 patent, 24:23-28.

Consistent with the intrinsic record, Zydus’s proposed construction of these terms requires that these terms be construed similarly to a “product-by-process” claim. That is to say, for purposes of invalidity, it is not necessary that the prior art disclose the claimed method for measuring a particular characteristic (here, impurity level) of the claimed product, only that it

discloses a product with the claimed characteristics. But for purposes of infringement, the claimed method must be used to determine whether a potentially infringing compound has the claimed characteristics. *See In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985).

For the '587 patent, Par states that the claims “are ‘product’ claims covering a tablet with certain characteristics.” *Supra*, 17. The tablet of claim 1 of the '587 patent has two characteristics: (1) less than 50 ppm of [N-nitroso-varenicline] impurity, and (2) less than 0.15% (w/w) of [diamide impurity]. For claim 1 of the '524 patent, the claimed method is directed to making a product with the characteristic of having less than 50 ppm of nitrosamine impurities. The claim term “as measured by [method],” however, is not a characteristic of the claimed product or method, as explained by the USPTO examiner during the prosecution of the asserted patents. Specifically, during prosecution, the Examiner stated:

Wei [the prior art reference] encompasses purifying varenicline free base by addition of an acid to obtain less than 25 ppm of N-nitroso varenicline as measured by HPLC-MS as recited by (a) of instant claim 25; the addition of tartaric acid to form varenicline tartrate as recited by (b) of instant claim 25; and forming a tablet having less than 25 ppm N-nitroso varenicline impurity as measured by HPLC-MS as recited by (c) of instant claim 25.

Wei doesn't teach [ ] that the concentration of N-nitroso impurity is measured by LC-ESI-HRMS (U.S. FDA method) as recited by instant claims 1 and 18.

***However, the claims are drawn to a product, not to a process.*** Wei does teach a tablet composition comprising varenicline tartrate having less than 50 ppm of N-nitroso-varenicline as recited by claims 1 and 18. It would have been prima facie obvious, in the absence of evidence to the contrary, that the tablet composition taught by Wei [as measured by a different method] would have had the same characteristics as recited by instant claims 1 and 18. See MPEP [2113](I):

***“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”*** *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). . . .

JA637 (“’587 patent prosecution history, Apr. 17, 2023, Non-Final Rejection”) at JA646-647, 7-8

(emphasis added).

The Examiner's reasoning makes sense: a product disclosed in the prior art having less than 25 ppm N-nitroso varenicline impurity as measured by HPLC-MS would be expected to have the characteristic of less than 50 ppm of N-nitroso-varenicline when measured by a different method, LC-ESI-HRMS (U.S. FDA method). *See, e.g.*, '587 patent, 3:43-46. In other words, for patentability, a characteristic of a product (here, less than 50 ppm of N-nitroso-varenicline) is independent of the method used to measure that characteristic.

Par did not take issue with the Examiner's interpretation of "as measured by [method]" or argue that the "as measured by [method]" claim limitation provides any weight for patentability. Instead, Par amended the claims to add other claim limitations. For example, Par amended then pending claims 1 and 24 as follows:

wherein the tablet comprises less than 50 ppm of N-nitroso-varenicline impurity  
 [] as measured by LC-ESI-HRMS *and less than 0.15% (w/w) of diamide []*  
*impurity as measured by RS Method-II.*

JA515 ("587 patent prosecution history, July 11, 2023, Remarks") at JA528, 12 (italics original, highlighting the amended claim limitation). Par argued that "[the prior art reference] Wei does not teach or disclose a varenicline tartrate tablet that contains less than 0.15% (w/w) of diamide impurity" and did not argue for patentability based on the "as measured by [method]" claim limitation. *Id.* Par's actions during prosecution support Zydus's proposed construction that for purposes of invalidity, it is not necessary that the prior art disclose the claimed method for measuring a particular characteristic of the claimed product, only that it discloses a product with the claimed characteristics. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.")

Zydus's proposed construction is consistent with MPEP 2113(I), which the Examiner

cited during the prosecution of the '587 patent:

***“The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”*** *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). . . . Furthermore, “[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes.” *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1370 n.14, 92 USPQ2d 1289, 1312, n.14 (Fed. Cir. 2009). *See also Purdue Pharma v. Epic Pharma*, 811 F.3d 1345, 117 USPQ2d 1733 (Fed. Cir. 2016). ***However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim.*** *Id.* at 1370 (“a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim”).

(emphasis added).

Similar to a product-by-process claim, where the patentability of a product does not depend on its method of production, the characteristic of a product (e.g., having an impurity at less than 50 ppm) does not depend on the method of measuring that characteristic for purposes of patentability. However, in the context of an infringement analysis, where the claim requires that a characteristic be measured by a specific method, infringement can only be found where that measurement method is used.

Par’s proposed construction that “[t]he claims do not require the accused infringer to use the methods recited in the claims to measure the impurity” is improper, because “to construe the claims in the manner suggested by [Par] would read an express limitation out of the claims.”

*Texas Instruments Inc. v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993); *see also, Becton, Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) (claims must be “interpreted with an eye toward giving effect to all terms in the claim”) (internal citations omitted). Par seems to acknowledge that the recited methods are necessary to

show infringement, noting that the claimed “characteristics” (i.e., impurity levels) are only present “if measured using specific methods.” *Supra*, 17.

Par’s attempts to distinguish its claims from product-by-process claims misses the point. Zydus is not arguing that the claims are, in fact, product by process claims—only that the “as measured by [method]” claim terms are akin to a product-by-process claim in that they are simply the means by which the claimed impurity characteristics are measured, and thus do not impart patentability.

### 3. Par’s Reply Position

Zydus concedes it is “not arguing that the claims are, in fact, product by process claims.” *Supra*, III.B.2. Zydus nevertheless contends that the claims should be construed “similarly to a ‘product-by-process’ claim.” *Id.* Zydus cites zero law that supports applying product-by-process rules in this circumstance. Indeed, without any precedent, Zydus is asking the Court to adopt *two* opposite constructions for these claims—one for validity and one for infringement.

As to invalidity, Zydus wants to read the “as measured by” limitations entirely *out of the claim*. Zydus asserts—without support—that a “characteristic of a product . . . is independent of the method used to measure that characteristic.” *Id.* But here, the claims *specify the method* used for measurement. *See* ’587 patent, 24:23-28. In effect, Zydus is asking this Court to determine—at *Markman* with no factual record—that any prior art reference using a *different* measurement method, and which reports a ppm or (w/w) percentage within the claim limit, anticipates. That is inappropriate. A claim construction should generally attempt to “give meaning to all the words in [the] claims,” *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995), and avoid “reading out” words from the claim. *See Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 24–25 (Fed. Cir. 2000).

For infringement, Zydus takes the *opposite* view: “infringement can only be found where that measurement method is used.” *Supra*, III.B.2. But the “as measured by” limitations are not process limitations; they simply recite the means of measuring the impurity level in the tablets. The infringement inquiry is simple: Par must show that Zydus’s product would more likely than not meet the claimed impurity limitations if measured by the claimed measurement methods. Par could do this by testing the tablets using the claimed measurement technique, or Par could provide expert testimony demonstrating that the claimed testing method would be expected to give the same result as Zydus’s testing methods. Zydus acknowledges that an impurity measurement with a different technique might establish anticipation of the “as measured by” limitations. *Id.* Zydus can make such arguments for validity and Par may make such arguments for infringement. But there may also be instances where a different method would produce different results. This is the domain of expert testimony, not *Markman*.

The ’587 prosecution history does not support Zydus. The Examiner expressly noted that the “claims are drawn to a product, not a process.” JA646-647. As part of a non-final rejection, the Examiner took the position that measurement technique used on tablets in Wei “would have the same characteristic” as the claimed measurement method. *Id.* The Examiner thus understood that the tablet composition taught by Wei would need to have the same characteristic *if measured by the claimed measurement methods* to anticipate the claims.<sup>6</sup>

#### 4. Zydus’s Sur-Reply Position

Zydus is not asking for opposite constructions. *Supra*, 22. This Court has made clear that “[w]hile process limitations need not be met to prove invalidity of a product-by-process

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<sup>6</sup> Zydus make much of the Examiner citing to product-by-process case law and MPEP 2113(I). But Zydus admits the claims are not product-by-process claims. And the MPEP does not govern district courts. *See Molins PLC v. Quigg*, 837 F.2d 1064, 1067 (Fed. Cir. 1988).

claim, the meaning of a claim term, even in a product-by-process claim, is the same for all purposes.” *Advanced Biologics LLC v. Zimmer Biomet Spine, Inc.*, 2022 WL 1773672, at \*4 (D. Del. June 1, 2022). Par cites no authority to support its construction, which vitiates the recited methods for infringement.

The prosecution history supports Zydus’s position. *Supra*, 19-21. The Examiner’s reasoning—a prior art product having the claimed impurity level measured by a different method would be expected to have the claimed impurity characteristic measured by the claimed method—fully supports Zydus’s position: an old product having the same characteristics is not patentable even if the characteristics are measured by a different method. *See Supra*, 19; *Kamstrup A/S v. Axioma Metering UAB*, 43 F.4th 1374, 1381 (Fed. Cir. 2022) (“In determining validity ... the focus is on the product [itself]. That is because of the ... longstanding rule that an old product is not patentable even if it is made by a new process.”). Par never objected to this reasoning during prosecution.

Zydus is not attempting to read this limitation out of the claim. *Supra*, 22. Par’s patent is directed to a method of making a known compound having certain levels of impurities, not a novel testing process. Par does not argue that there is anything about the recited measurement method that imparts patentability. The law is clear that an old product is not patentable even if it is made by a new process. *Amgen*, 580 F.3d at 1370.

**C. “Means for Reducing the Nitrosamine Impurities” (’524 Patent, claim 1)  
 “Means for Removing the Nitrosamine Impurities” (’524 Patent, claim 12)  
 “Employing an Acid-Base Treatment to Remove the Nitrosamine Impurities”  
 (’524 Patent, claims 18 and 26)**

<b>Par Proposed Construction</b>	<b>Zydus Proposed Construction</b>
Plain and ordinary meaning	“means for reducing the amounts of the nitrosamine impurities, wherein the amounts

<p>To the extent the Court requires a construction, “a step or steps taken to contribute to the reduction of nitrosamine impurities,” as defined later in the claim.</p> <p>(To the extent Zydus’s construction would require a single means for reducing nitrosamine impurities, the claim is not so limiting.)</p>	<p>of nitrosamine impurities are decreased by the means”</p>
<p>Plain and ordinary meaning</p> <p>To the extent the Court requires a construction, “a step or steps taken to contribute to the removal of nitrosamine impurities,” as defined later in the claim.</p> <p>(To the extent Zydus’s construction would require a single means for removing nitrosamine impurities or that the means remove all nitrosamine impurities, the claims are not so limiting.)</p>	<p>“means for removing the nitrosamine impurities, wherein the nitrosamine impurities are removed by the means”</p>
<p>Plain and ordinary meaning</p> <p>To the extent the Court requires a construction, “employing a process to separate a desired substance from nitrosamine impurities via treatment with an acid and subsequent treatment with a base to contribute to the removal of nitrosamine impurities.”</p>	<p>“employing an acid-base treatment to remove the nitrosamine impurities, wherein the nitrosamine impurities are removed by the acid-base treatment”</p>

### 1. Par’s Opening Position

The purpose of claim construction is to aid the fact finder in understanding the scope of the claims. Absent certain strictly delineated circumstances, the Court should give claim terms their plain and ordinary meaning, which is the meaning that the term would have to POSA at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). Here the claim terms stand on their own and require no construction to understand their ordinary meaning. With respect to claim 1, the claim requires a “means for reducing the nitrosamine impurities to less than 50 ppm per tablet” with the claim later specifying that the means “comprises an acid base treatment.” ’524 patent, cl. 1. With respect to claim 12, the claim

requires a “means for removing the nitrosamine impurities in the varenicline tartrate to less than 50 ppm,” with the claim later specifying that the means “comprises an acid-base treatment.” *Id.*, cl. 12. Claims 18 and 26 require “employing an acid-base treatment to remove the nitrosamine impurities.” *Id.*, cls. 18, 26. There is no ambiguity in these claim terms that requires construction.

Where, as here, the terms at issue have readily understood meanings—such as “reducing” or “removing” nitrosamine impurities—the Court need not attempt to restate the limitation in other words. Rather, the Court may confirm that they each are to be given their ordinary meaning without the additional qualifiers Zydus attempts to read into the claim. *See, e.g. Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015) (noting the term at issue “is comprised of commonly used terms; each is used in common parlance and has no special meaning in the art,” and “[b]ecause the plain and ordinary meaning of the disputed claim language is clear, the district court did not err by declining to construe the claim term”); *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1380 (Fed. Cir. 2001) (“The defendants argue that the court committed reversible error by refusing to construe the claim terms ‘irrigating’ and ‘frictional heat.’ . . . We agree with [plaintiff] that the district court did not err in relying on the ordinary meaning of these terms.”).

On the other hand, Zydus seeks to add qualifiers that insert ambiguity where none exists. In claim 1, Zydus proposes adding “wherein the amounts of nitrosamines are decreased by the means.” In claims 12, 18, and 26, Zydus proposes adding “wherein the nitrosamine impurities are removed by the [means/acid-base treatment].” Despite this Court’s requirement to explain the importance of a particular construction, Zydus has failed to do so. In the Joint Claim Construction Chart, Zydus cites nearly the entire substantive prosecution history of the ’524

patent without any explanation of what specific passages support its proposed construction. Accordingly, Par is left to guess what distinction Zydus attempts to draw with its proposed construction or what ambiguity it attempts to resolve.

## 2. Zydus's Answering Position

Par insists that “[t]here is no ambiguity in these claim terms that requires construction.” and that they should be given their “plain and ordinary meaning.” *Supra*,26. But Par’s attempts to construe the “plain and ordinary meaning”—in particular its refusal to agree that these terms require “reducing” or “removing” nitrosamine impurities *at all*—create ambiguity. It is entirely unclear what it means for a “step or steps” to “contribute to” reducing or removing nitrosamine impurities in Par’s proposed construction.

Zydus’s proposed constructions resolve this ambiguity and are supported by the specification and prosecution history of the ’524 patent. The ’524 patent is directed to the use of an acid-base treatment to remove or reduce the nitrosamine impurities. *See* ’524 patent at Abstract and Claims. Specifically, the ’524 patent specification discloses (emphasis added):

- the process **results** in varenicline tartrate having less than 100 ppm of N-nitroso-varenicline impurity per 1 mg of varenicline free base, or per 0.5 mg varenicline free base, or less than 50 ppm, or less than 25 ppm, or less than 10 ppm, or less than 5 ppm, ’524 patent, 1:64-2:1;
- [t]he crude [varenicline] **is purified** by acid-base treatment to remove nitrosamine impurities, *id.* at 15:62-65;
- [t]he salts are formed in-situ and salts are dissolved in the aqueous phase and the **undissolved nitrosamine is extracted in an organic solvent to eliminate** the nitrosamine impurities, *id.* at 21:16-19; and
- [t]he nitrosamine impurities are substantially or completely eliminated by converting the varenicline base into varenicline salt with an organic or inorganic acid having a pKa between 2 and 6. Because the absence of basic nitrogen due to the presence of the nitroso group prevents the nitrosamine impurities to form salt of acids, nitrosamine impurity fails to dissolve in the aqueous solution, and could be extracted in an organic solvent. Thus, **nitrosamine impurities could be completely removed in this acid-base treatment process**, *id.* at 22:20-30.

Based on the specification, it is clear that the claimed methods not only require the “means

for reducing” (’524 patent, claim 1), “means for removing” (’524 patent, claim 12), and “employing an acid-base treatment to remove” (’524 patent, claims 18 and 26) steps, but also require that the nitrosamine impurities are actually decreased/removed by the recited steps.

In contrast, the specification does not contain any discussion of a particular step “contributing to” reducing or removing nitrosamine impurities. Par’s proposed addition of “contribute to” only confuses, rather than clarifies, the meaning of these terms. *See Active Video Networks v. Verizon Commc’ns*, 694 F.3d 1312, 1325-26 (Fed. Cir. 2012) (rejecting claim construction that would be “confusing, unhelpful, adds no clarity to the claim language itself”).

The prosecution history also supports Zydu’s proposed construction. During the prosecution, Par expressly discussed the use of the claimed “means” or “acid-base treatment” to achieve the intended purpose of reducing or removing nitrosamine impurities. For example, to distinguish the prior art Wei reference, Par argued that “Wei does not teach the claimed acid-base treatment, *i.e.*, Wei does not teach that an acid can be used to perform a layer separation wherein the aqueous layer would contain a substantially pure varenicline tartrate product and the organic layer would contain the water insoluble nitrosamine impurities.” JA548 (“’524 patent prosecution history”), Mar. 29, 2023, Remarks at JA650, 11, *see also id.* at JA648-650, 9-11 (providing the general scheme of the acid-base treatment). That is, Par argued during prosecution that the claimed “means” or “acid-base treatment” achieves the intended purpose of removing nitrosamine impurities, and cannot now argue that the nitrosamine impurities are not necessarily decreased/removed by the “means” comprising “acid-base treatment.” *See Springs*, 323 F.3d at 995 (“The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.”)

### 3. Par's Reply Position

Par's position is that the plain and ordinary meaning of "means for reducing" or "means for removing" should govern. Contrary to Zydus, Par is not suggesting that nitrosamine impurities need not be "actually reduced/removed" by the acid-base treatment. *Supra*, III.B.2. That is the plain and ordinary meaning of "reduce" or "remove."

Lacking notice, Par attempted to guess Zydus's reasons for its construction, and explained that a construction that required either the acid-base treatment to be the *sole* means for reducing impurities or that the acid-base treatment completely remove the nitrosamine impurities would be wrong. Although Par's Opening put Zydus on notice, Zydus never clarified its position, so Par is still left guessing. Given its failure to engage in a timely manner, Zydus should not be permitted to further elaborate its position on surreply.

If Zydus contends that the claimed acid-base treatment needs to be the *sole* means used to reduce or remove nitrosamine impurities, that position would be unjustified. The claims are "comprising" claims and the "means comprises an acid-base treatment." *See* '524 patent, cls. 1, 12, 18, 26. Thus an accused infringer's manufacturing process may involve other means of also reducing or removing nitrosamine impurities. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed.Cir.1997) ("Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.").

### 4. Zydus's Sur-Reply Position

Zydus's construction does not require that the acid-base treatment needs to be the sole means to reduce or remove nitrosamine impurities, only that it actually reduces/removes the impurities. Par concedes that, contrary to its construction (only requiring "contribution" to reducing impurities), "Par is not suggesting that nitrosamine impurities need not be 'actually

reduced/removed’ by the acid-base treatment.” *Supra*, 28-29. That is consistent with Zydus’s construction. The Court should therefore adopt Zydus’s construction.

**D. “an acid-base treatment” (’524 Patent, claims 1, 12, 18 and 26)**

<b>Par Proposed Construction</b>	<b>Zydus Proposed Construction</b>
Not indefinite; plain and ordinary meaning	Indefinite
To the extent the court requires a construction, “a process to separate a desired substance from an undesired substance via treatment with an acid and subsequent treatment with a base.”	To the extent the court requires a construction, “an acid-base treatment that extracts the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase”

**1. Par’s Opening Position**

Zydus proposes that the phrase “acid-base treatment” cannot be understood by a POSA, or in the alternative, that the Court should construe the phrase to improperly import limitations from the specification. The Court should reject both of Zydus’s arguments. Zydus cannot establish by clear and convincing evidence that a POSA would not reasonably understand the scope of an “acid-base treatment.” Zydus’s alternative argument violates fundamental claim construction principles cautioning against importing limitations from a preferred embodiment into a claim.

**a. The Court Should Afford the Term “Acid-Base Treatment” Its Plain and Ordinary Meaning to a POSA**

The claims themselves are the starting and focal point in ascertaining the meaning of particular claim terms to a person of skill in the art. *See Phillips*, 415 F.3d at 1312-14; *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (“In claim construction, this court gives primacy to the language of the claims”). Moreover, “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent

application.” *Phillips*, 415 F.3d at 1313. Here, an acid-base treatment has an ordinary meaning to a POSA: a process to separate a desired substance from an undesired one by treatment with an acid to form a salt followed by a subsequent treatment with a base to break the salt. The Court should afford the term its plain and ordinary meaning.

**(1) The Plain and Ordinary Meaning of Acid-Base Treatment and Underlying Chemical Principles**

Acid-base treatments are a common, well-known technique in chemistry which is used to purify certain compounds of interest. Dodds Decl., JA192, ¶¶ 20-21. Ordinarily skilled artisans in the relevant art understand that acid-base treatments work by creating a distinction in the chemical or physical properties between substances that can be then exploited to separate the two. JA195-196, ¶¶ 27-28. An acid-base treatment relies on differences in solubilities between free bases and salts,<sup>7</sup> with salts generally soluble in water (or aqueous solutions) and free bases generally more soluble in organic solvents. JA194-196, ¶¶ 26-28. An acid-base treatment can be used when one of the substances can react with an acid to form a salt and the other substance cannot. *Id.* In such circumstances, an acid-base treatment can be implemented to convert the desired compound into a salt by addition of an acid (here tartaric acid), then taking advantage of differences in solubility between the desired compound (varenicline) and the impurity which cannot form a salt (here varenicline nitrosamine) in various solvents. JA193-197, ¶¶ 24-30. An

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<sup>7</sup> A “free base” in this context means a compound with an amine function, that is, a nitrogen atom bonded to one or more carbon atoms (two carbon atoms in the case of varenicline free base) which is capable of forming a salt with an acid, but is present in the form that is not a salt. If the nitrogen atom, which is basic in nature, were found combined with an acid, and thus in the form of a salt, then that nitrogen atom would have combined with a proton from the acid to form a positively charged species, balanced by the negatively charged acid that has given up the proton. In the free base form, the basic nitrogen atom has not accepted a proton from an acid, as no acid is present. Thus, the nitrogen atom is “free” of any acid, and is termed a “free base.” Dodds Decl., JA193-194 ¶ 24, n. 3.

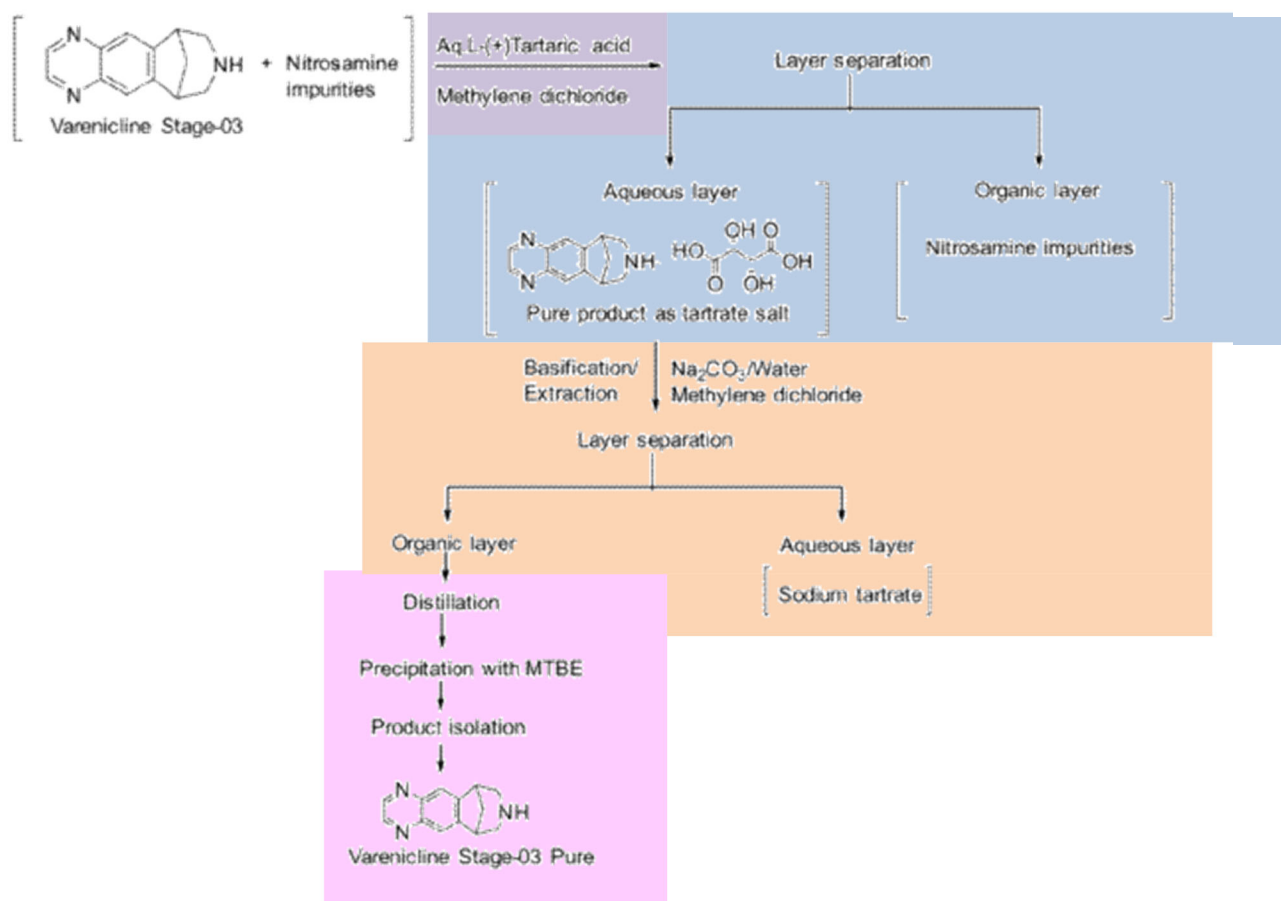
acid-base treatment concludes by treatment with a base to break the salt, returning the desired compound to its purified free base form. *Id.*, JA195-196, ¶ 28. Treating with an acid to make a salt followed by subsequent treatment with a base to break a salt, is commonly referred to as an acid-base treatment and used as a purification tool. JA197-198, ¶ 31 (citing Dodds Decl., Ex. D (US 2019/0185471), JA276, ¶ [287] (“acid-base treatment i.e., salt making and breaking”)); *id.*, ¶ 32, (citing Dodds Decl., Ex. E (WO2011021214), JA305-306, 2:17-3:18 (referring to an acid-base treatment as “purification by treating it with an [sic] suitable acid and subsequent treatment with a suitable base”)).

With the above principles in mind, varenicline tartrate is a salt resulting from the basic nitrogen atom described above accepting a proton from the tartaric acid and thus becoming positively charged. JA193-194, ¶ 24. This is electrically balanced by the tartaric acid molecule that has given up the proton and has itself become negatively charged. *Id.* The resulting combination of a positively charged cation with a negatively charged anion is a salt. *Id.* Thus, varenicline free base is just the varenicline molecule itself, in an electrically neutral form, while varenicline tartrate salt is the combination of varenicline and tartaric acid. *Id.* The varenicline tartrate salt is more soluble in water (or aqueous solutions) whereas the varenicline free base is more soluble in organic solvents. JA194-195, ¶ 26. The ’524 patent explains that nitrosamines cannot form a salt under the same conditions as varenicline. JA194, ¶ 25; ’524 patent, 22:20-27. This results in the varenicline tartrate having different solubility properties than the nitrosamine impurities, which can be exploited to separate the two. JA193-196, ¶¶ 24-29.

## (2) The ’524 Patent Describes a Non-limiting Example of an Acid-Base Treatment

The ’524 patent describes, but is not limited to, one example of a common form of acid-base treatment involving the use of aqueous and organic solvents and separation of the two liquid

layers that form during the process. This acid-base treatment is used to purify varenicline free-base, which can be subsequently synthesized into varenicline tartrate and incorporated into tablets with low levels of nitrosamine impurities. The '524 patent illustrates the acid-base treatment of crude varenicline free base in Figure 1 (color added):



**Figure 1**

As can be seen in Figure 1, the non-limiting embodiment of an acid-base treatment in the '524 patent starts with crude varenicline free base (Varenicline Stage-03) and ends with pure varenicline free base by treating the free base with acid to form a salt and subsequently treating with a base to break the salt. It does this by: (1) dissolving crude free base with an organic solvent and adding an aqueous solution of tartaric acid to make the varenicline tartrate salt

(purple box), (2) separating the layers which have different densities, keeping the varenicline tartrate in the aqueous layer and discarding the organic layer that contains nitrosamine impurities (blue), (3) further isolating the varenicline tartrate in the aqueous layer by breaking the varenicline salt, which is achieved by basifying (increasing the pH) of the aqueous solution and adding an organic solvent that results in the varenicline tartrate reverting to its free base form and concentrating in the organic layer instead of the aqueous layer (orange), and (5) replacing the organic solvent with tertiary butyl methyl ether to cause the purified varenicline free base to precipitate out of the organic layer (i.e. form a solid within the organic solvent), where it can be isolated by filtration (pink). *See* JA196-197 ¶¶ 29-30; '524 patent, Fig. 1, 12:60-17:17, 37:53-42:34, 65:1-49, 68:18-69:10.

Acid-base treatments constitute a class of chemical processes known to chemists. Although the specific example of an acid-base treatment described in the '524 patent is implemented using aqueous and organic solvents to form separable liquid layers, there is no basis to limit the meaning of the term to that single example. *See Phillips*, 415 F.3d at 1323 (“In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.”). A POSA would recognize that “acid-base treatment” is broader than the specific liquid-liquid layer separation example described in the '524 patent. JA197-198 ¶¶ 31-32. This includes acid-base treatments that utilize a single solvent instead of two. In such acid-base treatments, the desired substance can be separated from the undesired substance via precipitation and filtration. For example, a free base can be dissolved in an organic solvent and treated with non-aqueous acid to form a salt. JA198-201 ¶¶ 32-35. The impurities would remain dissolved in the organic solvent and the salt—which is no longer soluble in an organic solvent—would precipitate out of

the solution. *Id.* This solid form of the salt can then be collected via several means such as filtration. *Id.* The salt can then be basified in an organic solution to break the salt and return to a purified free base form. *Id.* In such an example, an acid-base treatment has been performed using all the same principles discussed above without liquid-liquid layer separation or an aqueous solvent. *Id.* A POSA would still consider such a purification process as an acid-base treatment. *Id.*

Accordingly, because the term “acid-base treatment” has a plain and ordinary meaning to a POSA, the Court should construe the term to have its plain and ordinary meaning: a process to separate a desired substance from an undesired substance via treatment with an acid to form a salt and subsequent treatment with a base to break the salt.

**b. An “Acid-Base Treatment” Is Not Indefinite to a POSA**

Indefiniteness is a question of law with underlying factual determinations. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015). To establish that a claim is indefinite, a patent challenger must prove by clear and convincing evidence that the claim at issue, viewed in light of the specification and prosecution history, fails to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 572 U.S. at 910. The law does not require absolute precision. *Id.*; *Sonix Tech. Co. v. Publ’ns Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017). Moreover, because “patents are not addressed to lawyers, or even to the public generally, but rather to those skilled in the art,” a patent need not explain information that is already well known in the art. *Nautilus*, 572 U.S. at 909 (quotation omitted); *see Wellman, Inc. v. Eastman Chemical*, 642 F.3d 1355, 1367-68 (Fed. Cir. 2011). Zydus cannot meet its high burden to establish that the asserted claims of the ’524 patent are invalid for indefiniteness.

The indefiniteness inquiry “in many though not all cases, requires factual inquiries into the skilled artisans’ understanding.” *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 809 F.3d 1223, 1225 (Fed. Cir. 2015) (Moore, J. concurring); see *Teva Pharms.*, 574 U.S. at 331-33. Here, a POSA would be someone with an advanced degree in chemistry and several years’ experience synthesizing active pharmaceutical ingredients for use in pharmaceutical products. JA191-192 ¶¶ 18-19. Such a person would have expertise in concepts such as solubility and acid-base chemistry. As described above and in the accompanying declaration of Dr. Dodds, in this context, the phrase “acid-base treatment” has a well understood meaning to POSAs. *Id.*, ¶ 20.

Accordingly, when properly accounting for the knowledge of a POSA, the term “acid-base treatment” is sufficiently definite and has a well understood meaning in the field. To the extent Zydus argues otherwise, such argument would present factual questions underlying the ultimate indefiniteness legal question. Such important questions of fact are better resolved by the jury on a full record. See *Bombardier Recreational Products Inc. v. Arctic Cat Inc.*, 785 F. App’x 858, 867 (Fed. Cir. 2019) (holding that the question of definiteness was properly before the jury when its resolution turned on factual issues such as the state of the knowledge of a skilled artisan.).

**c. Zydus’s Alternative Construction Is Wrong**

**(1) The Plain Meaning of “Acid-Base Treatment” to a POSA Controls**

Claim terms are afforded their ordinary meaning except when (1) a patentee sets out a definition and thereby acts as his own lexicographer or (2) the patentee disavows the full scope of the claim term either in the specification or during prosecution. See *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d. 1367, 1371 (Fed. Cir. 2014). “The standards for finding lexicography

and disavowal are exacting.” *Id.* at 1371. For lexicography, “a patentee must clearly set forth a definition of the disputed term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Id.* (internal quotations omitted). Similarly, disavowal requires proof of clear “expressions of manifest exclusion or restriction.” *Teleflex, Inc. v. Ficosa North Am. Corp.*, 299 F.3d 1313, 1325-26 (Fed. Cir. 2002).

As explained above, an “acid-base treatment” has a well understood meaning in the art to refer to a purification method that involves treatment with an acid to form a salt followed by a subsequent base treatment to break the salt. This technique can be implemented to separate a desired substance from an undesired one. Zydus does not contend in the joint claim construction chart that its alternative construction constitutes the plain and ordinary meaning of “acid-base treatment” to a POSA. D.I. 58 at 3-4. Nor does Zydus’s alternative construction attempt to clarify a purported ambiguity in the term “acid-base treatment.” In fact, Zydus’s construction repeats the phrase “acid-base treatment” and goes on to add that the term should be narrowed to acid-base treatments that “extract[] the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase.” Thus, Zydus tacitly acknowledges that the plain and ordinary meaning of “acid-base treatment” is broader than its proposed construction and therefore bears a heavy burden in trying to prove that the Court should deviate from the ordinary meaning of the claims.

As noted above, Zydus has cited nearly the entire substantive prosecution history of the ’524 patent along with large swaths of the specification without any explanation of what specific passages support its proposed construction. Accordingly, again Par is left to guess whether Zydus is arguing that Par acted as its own lexicographer or disavowed claim scope. To the extent Zydus does make such an argument, it cannot meet its heavy burden to deviate from the

plain and ordinary meaning of “acid-base treatment.” The Court should reject Zydus’s fallback invitation to rewrite the claims and afford the term its plain and ordinary meaning.

**(2) Zydus’s Construction Improperly Imports Limitation from the Specification into the Claims**

The Court should reject Zydus’s attempt to limit the claim to the examples in the specification for two additional reasons. First, each of the examples of an acid-base treatment described in the ’524 patent are described as non-limiting specific embodiments, not the invention as a whole. *See* ’524 patent, 13:16-25 (“In one specific embodiment...”), 14:25-34 (“In another specific embodiment”), 15:58-17:17 (“In another specific embodiment”), 32:45-59 (specifying that the examples are “illustrative and not in a limiting sense”). Thus, construing the claims to require aqueous and organic solvents and layer separation would improperly deviate from the plain and ordinary meaning of the term and import limitations from the specification into the claims. *See Deere*, 703 at 1354 (“While claim terms are understood in light of the specification, a claim construction must not import limitations from the specification into the claims.”); *Innova/Pure Water*, 381 F.3d at 1117 (“[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect.”). Indeed, even as here, where the patent describes a single embodiment of an acid-base treatment, the Federal Circuit “has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as limited to that embodiment.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004).

Second, a construction of acid-base treatment requiring both aqueous and organic solvents and layer separation would be inconsistent with dependent claims in the ’524 patent and would render them superfluous. As the Federal Circuit explained in *Phillips*, “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in

question is not present in the independent claim.” 415 F.3d at 1314-15. This presumption is especially strong when, as is the case here, “the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003); *see also Cydex Pharmaceuticals, Inc. v. Alembix Global Holdings SA*, 19-cv-956-LPS, 2020 WL 6393918, at \*1 (D. Del. Nov. 2, 2020) (Stark, J.) (citing *SunRace*).

Independent claims 1, 12, 18, and 26, all refer to an “acid-base treatment” generally. Dependent claims 6, 13, and 20 (represented below with emphasis) add the very limitations that Zydus seeks to add to the general construction of “acid-base treatment”:

**6.** The method of claim 1, wherein the acid-base treatment comprises:

(a) converting the varenicline free base into a varenicline salt with an organic or inorganic acid in *an aqueous solution*;

(b) *extracting the nitrosamine impurities with an organic solvent*; and

(c) isolating purified varenicline free base by adding a base to the aqueous solution and extracting the purified varenicline free base with an organic solvent.

**13.** The method of claim 12, *wherein the means further comprises layer separation*.

**20.** The method of claim 18, *further comprising layer separation* and wherein the acid-base treatment and layer separation comprises:

(a) converting the varenicline free base into a varenicline salt with an organic or inorganic acid in an *aqueous solution*;

(b) *extracting the nitrosamine impurities with an organic solvent*; and

(c) isolating purified varenicline free base by adding a base to the aqueous solution and extracting the purified varenicline free base with an organic solvent.

'524 patent, cls. 6, 13, 20. As can be seen in the limitations added by dependent claims 13 and 20, the phrase “acid-base treatment” is broader than techniques that utilize two different solvents to form layers that can be separated. Otherwise, there would be no need to add dependent claims, such as claim 13, adding only that the acid-base treatment “further comprises layer separation.” *Id.*, cl. 13. Accordingly, per *Phillips* and *SunRace*, the '524 patent dependent claims create a strong presumption that the phrase “acid-base treatment” is broader than techniques involving layer separation and that the Court should not read layer separation into the independent claims. Similarly, the same dependent claims create a heavy presumption against Zydus's effort to read into the construction of “acid-base treatment” that the “varenicline product<sup>8</sup>” is extracted into an aqueous phase while leaving the nitrosamine impurities in the organic phase. If that were the case, there would be no need for dependent claims such as 6 and 20 to further specify that the varenicline salt be formed via an acid in an aqueous solution or that the nitrosamine impurities be extracted in an organic solvent.

## **2. Zydus's Answering Position**

### **a. The '524 patent specification supports Zydus's proposed construction**

Although the specification does not expressly define the term “acid-base treatment,” it uses this term to describe a process for removing impurities, in particular nitrosamine impurities, from crude varenicline. For example, the '524 patent discloses:

- purifying crude 7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine by acid-base treatment substantially eliminate impurities and to

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<sup>8</sup> Zydus's proposed construction adds further ambiguity as it is unclear what Zydus is referring to as the “varenicline product.”

form purified 7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine, '524 patent, 2:27-31; and

- crude 7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine (crude Stage III—Varenicline Free Base) is purified by acid-base treatment to remove nitrosamine impurities, *id.* at 13:16-19.

The '524 patent further discloses how nitrosamine impurities can be removed by the acid-base treatment: “Because the absence of basic nitrogen due to the presence of the nitroso group prevents the nitrosamine impurities to form salt of acids, nitrosamine impurity fails to dissolve in the aqueous solution, and could be extracted in an organic solvent. Thus, nitrosamine impurities could be completely removed in **this acid-base treatment process.**” *Id.* at 22:23-30 (emphasis added).

There is no dispute that the '524 patent specification only describes a single type of acid-base reaction: where varenicline base is treated with an acid to form a salt, varenicline tartrate is extracted into an aqueous phase, and the nitrosamine impurities are extracted into an organic phase. *See supra*, 32-35; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 65:51-68:42 and Table 23. The '524 patent discloses:

- Example 3: dissolving crude free base with methylene chloride (an organic solvent) and adding an aqueous solution of tartaric acid to make the varenicline tartrate salt, extracting the varenicline tartrate into the aqueous phase while leaving the nitrosamine impurities in the methylene chloride (organic) phase; *see supra*, 33-34; *see also* '524 patent, Fig. 1, 40:54-41:4;
- Example 12: “A solution of Varenicline free base (50.0 g) in methylene dichloride (250 mL) was stirred with the aqueous solution of L-(+)-Tartaric acid (1.2 eq, 39.08 g in 250 mL of water). The aqueous layer containing Varenicline tartrate salt was stirred with methylene dichloride (3×150 ml) to remove the nitrosamine impurity by solvent extraction. Thereafter, follow the general procedure for the isolation of Varenicline base from the aqueous layer;” *id.* at 65:51-61, Table 23;
- Examples 13-20, using a similar process as Example 12 while using different acids (fumaric acid, lactic acid, malic acid, malonic acid, hydrochloric acid, succinic acid, oxalic acid, and citric acid, for Examples 13-20, respectively); *id.* at 65:63-68:42, Table 23.

A POSA would understand that this “acid-base treatment” of partitioning the varenicline

from the nitrosamine impurities is akin to an “acid-base extraction”—a fundamental organic chemistry subject. Baertschi Declaration, JA367, 371, ¶¶59, 68. Although a POSA would know that there are other types of acid-base extractions, they would understand based on these disclosures and prosecution history, discussed below, that the term “acid-base treatment” in the ’524 patent is limited to a process that extracts the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase.

**b. During prosecution, the patentees disclaimed “acid-base treatments” beyond the type disclosed in the specification**

During the prosecution of the ’524 patent, Par amended claim 1 to include the “acid-base treatment” claim limitation and argued that “[n]one of the cited references teach or suggest such acid-base treatment.” ’524 patent prosecution history, Mar. 29, 2023, Remarks at JA558, 9. Par also stated that “[a]s detailed in Figures 1, 11 and Table 3 of Applicant's specification, the acid-base treatment employs an organic solvent and layer separation to remove the water insoluble nitrosamine impurities.” *Id.* Par further stated that the prior art reference “Wei does not teach the claimed acid-base treatment, *i.e.*, Wei does not teach that an acid can be used to perform a layer separation wherein the aqueous layer would contain a substantially pure varenicline tartrate product and the organic layer would contain the water insoluble nitrosamine impurities.” *Id.* at JA560, 11. Par also provided a general scheme of the claimed acid-base treatment, which details extracting the varenicline salt into the aqueous phase while leaving the nitrosamine impurities in the organic phase. *Id.* at JA558-560, 9-11.

Par emphasized the importance of aqueous/organic layer separation to its alleged invention: “This is a critical difference from the presently claimed invention, which first converts varenicline free base to water soluble varenicline salt **and then** removes the water insoluble nitrosamines by layer separation using an organic solvent. No layer separation of the nitrosamines

is disclosed in Wei.” *Id.* at JA563,14 (emphasis added in bold, italics in original).

Par’s amendments and statements made during prosecution constitute an unmistakable disavowal of any “acid-base treatment” that does not extract the varenicline salt into the aqueous phase while leaving the nitrosamine impurities in the organic phase. *See e.g., Grober v. Mako Prods.*, 686 F.3d 1335, 1341 (Fed. Cir. 2012); *See AccuScan, Inc. v. Xerox Corp.*, 76 F. App’x 290, 291-92 (Fed. Cir. 2003) (“the doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution”); *Springs* 323 F.3d at 995 (“The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.”).

**c. There is no intrinsic evidence to support Par’s proposed construction**

Par’s proposed construction has two parts: “treatment with an acid” and “subsequent treatment with a base.” Par ignores that “treatment” suggests an effect and the claim tells us what this effect is— “reduc[ing] the nitrosamine impurities.” But in the ’524 patent, “treatment with an acid” is the only step that removes nitrosamine impurities, while the “subsequent treatment with a base” merely returns the varenicline to its free base form, which was present before the acidification. Baertschi Declaration, JA370, ¶64. In contrast to the numerous examples of using acids to remove nitrosamine impurities, the ’524 patent is devoid of any examples where “treatment with a base” is used to do the same. *Id.* at JA370-371, ¶66.

Finding nothing in the intrinsic evidence, Par relies on the declaration of its expert, Dr. Dodds, who further relies on two unrelated patent applications (US 2019/0185471 and WO2011021214) that simply use the term “acid-base treatment” without an express definition, to define the purported “plain and ordinary meaning” of the term “acid-base treatment.” *Supra*, 31-

32. Notably, Dr. Dodds does not cite any textbooks, treatises, or peer-reviewed articles that use or define this term.<sup>9</sup> In any event, “extrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language. Nor may it contradict the import of other parts of the specification.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). The term “acid-base treatment” cannot be construed in a vacuum—it must be construed in light of the patent specification in which it resides. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (“We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.”) As explained above, the specification describes only one type of acid base treatment and does not describe any of the alleged various alternative “acid-base treatments” about which Par contends a POSA would know.

Par argues that the term “acid-base treatment” should not be limited to “one example of a common form of acid-base treatment involving the use of aqueous and organic solvents and separation of the two liquid layers that form during the process.” *Supra*, 32. But Par acknowledges that *every* example of the claimed “acid-base treatment” in the ’524 patent—all eight of them—describe a process where varenicline is extracted into an aqueous phase and the nitrosamine impurities are extracted into an organic phase. *See* ’524 patent at 65:51-67:24 and Table 23; *see, e.g., Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) (“When a patent thus describes the features of the [alleged invention] as a whole, this

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<sup>9</sup> The Fujima article makes one reference only to “base treatment.” Yoshito Fujima et al., *Synthesis of (S)-3-(N-Methylamino)-1-(2-thienyl)propan-1-ol: Revisiting Eli Lilly’s Resolution–Racemization–Recycle Synthesis of Duloxetine for its Robust Processes*, Organic Process Research & Development, 2006, 10, 905-913 at 905 (“Fujima”); *see also* Baertschi Declaration, JA370, ¶65.

description limits the scope of the invention.”).

Par does not even attempt to address the patentees’ claim amendments and arguments to distinguish the prior art Wei reference. *See supra*, 37. The Federal Circuit has repeatedly held that when a patentee makes a “clear and unmistakable disavowal of scope during prosecution,” like Par did during the prosecution of the ’524 patent, a claim’s scope must be narrowed under the doctrine of prosecution disclaimer. *See e.g., Grober v. Mako Prods.*, 686 F.3d 1335, 1341 (Fed. Cir. 2012); *see AccuScan, Inc. v. Xerox Corp.*, 76 F. App’x 290, 291-92 (Fed. Cir. 2003) (“the doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution”); *Springs* 323 F.3d at 995 (“The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.”)

Par argues “[a] POSA would recognize that ‘acid-base treatment’ is broader than the specific liquid-liquid layer separation example described in the ’524 patent” and this “includes acid-base treatments that utilize a single solvent instead of two.” *Supra*, 34. But during prosecution of the ’524 patent, in order to overcome an obviousness rejection, Par argued against an acid-base treatment using a single solvent and emphasized the importance of using two solvents for layer separation (*i.e.*, liquid-liquid layer separation):

This is a critical difference from ***the presently claimed invention***, which first converts varenicline free base to water soluble varenicline salt *and then* removes the water insoluble nitrosamines by layer separation using an organic solvent. No layer separation of the nitrosamines is disclosed in Wei.

’524 patent prosecution history, Mar. 29, 2023, Remarks at JA563, 14 (emphasis added in bold, italics in original). Par cannot recapture what it surrendered during the prosecution. *Hilgraeve Corp. v. McAfee Assocs.*, 224 F.3d 1349, 1355 (Fed. Cir. 2000) (“prosecution history estoppel

bars recapture of subject matter surrendered during prosecution”); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 723 (2002) (holding that when the patentee narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised an unforeseen equivalent).

**d. Par’s proposed construction would render the claims invalid for lack of enablement and lack of written description**

The asserted claims of the ’524 patent require that the “acid-base treatment” remove or reduce nitrosamine impurities. *See* ’524 patent at Abstract and Claims. Par’s broad construction would render the asserted claims of the ’524 patent invalid under 35 U.S.C. § 112 for lack of enablement because the specification fails to provide a description of the claimed invention that is sufficient to enable a POSA to practice the full scope of the claims as construed by Par without undue experimentation. *See, e.g., Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344-48 (Fed. Cir. 1998) (affirming narrow claim construction because intrinsic evidence did not support a broader construction and broader construction could render patent vulnerable to attack for lack of enablement). “Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.” *Wyeth & Cordis Corp. v. Abbott Lab’ys*, 720 F.3d 1380, 1384 (Fed. Cir. 2013).

The only type of “acid-base treatment” disclosed in the specification is where the reaction product varenicline-acid salt is extracted into the aqueous phase through ionization, and the non-ionizable nitrosamine is left in the organic phase. *See, e.g.,* ’524 patent at 65:51-67:24, Examples 12-20. The ’524 patent does not describe how to make or use the alleged invention using any other acid-base treatment to reduce the nitrosamine levels. Baertschi Declaration, JA372-373 , 73. The best that Par can muster is one additional example of “acid-base treatments that utilize a single solvent instead of two.” *Supra*, 34. But Par provides no evidence that this type of “acid

base treatment” would remove nitrosamine impurities from varenicline, much less evidence that any other type of “acid base treatment” would do so. And as explained above, Par argued against a “single solvent” process during prosecution. Under Par’s proposed construction, a POSA could not practice the claimed methods to their full scope using acid-base treatments that are not disclosed in the ’524 patent to reduce nitrosamine impurity levels without undue experimentation. *Id.* at JA373, ¶74.

Par’s broad construction would also render the asserted claims of the ’524 patent invalid under 35 U.S.C. § 112 for lack of written description because a POSA would not have understood from the patent specification that the patentees possessed the full scope of the claimed subject matter as construed by Par. *See, e.g., Digital Biometrics*, 149 F.3d 1335 at 1344-48. Neither Par nor Par’s expert explains how the ’524 patent would provide sufficient written description for claims covering the use of any and all types of acid-base treatments to reduce or remove the nitrosamine impurities. *See Baertschi Declaration*, JA372-373, ¶73 (“[t]he specification does not contain examples of methods for removing nitrosamine impurities using acid-base chemistry aside from using an aqueous acid and partitioning the nitrosamine impurities into an organic layer. . . . The prosecution history of the ’524 patent is similarly limited”); *see also Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (“But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.”); *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed Cir. 2011) (“To satisfy the written description requirement, the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.”)

**e. The dependent claims do not save Par’s proposed construction.**

Par argues that “a construction of acid-base treatment requiring both aqueous and organic solvents and layer separation would be inconsistent with dependent claims in the ’524 patent and would render them superfluous.” Not so. For example, dependent claims 6 and 20 require “(a) converting the varenicline free base into a varenicline salt with an organic or inorganic acid *in an aqueous solution*.” Zydus’s construction does not require the varenicline salt to be converted in an aqueous solution—under Zydus’s construction, a POSA may convert the varenicline free base into a varenicline salt in an organic solution, an aqueous solution, or a mixture of both. Zydus’s proposed construction also does not require “(c) isolating purified varenicline free base by adding a base to the aqueous solution and extracting the purified varenicline free base with an organic solvent” as required by dependent claims 6 and 20. A POSA may also isolate purified varenicline free base by adding a base to the aqueous solution— instead of an organic solvent—to precipitate the varenicline free base. *See, e.g.*, ’524 patent, 13:63-14:8. As to claim 13, Zydus’s proposed construction only requires extracting varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase, even though a POSA could subsequently separate the layers into different containers.

Moreover, prosecution history disclaimer, as present here, can overcome the presumption of claim differentiation. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1097 (Fed. Cir. 2013).

For at least these reasons, Par’s proposed construction should be rejected.

**f. The term “acid-base treatment” is indefinite.**

The “acid-base treatment” limitation appears in independent claims 1, 12, 18, and 26 of the ’524 patent, and these claims separately require mixing varenicline with tartaric acid. For example, claim 1 reads:

1. A method of making a varenicline tartrate tablet comprising less than 50 ppm of nitrosamine impurities, the method comprising:
  - (a) mixing varenicline free base with tartaric acid to form varenicline tartrate; and
  - (b) means for reducing the nitrosamine impurities to less than 50 ppm per tablet as measured by LC-ESI-HRMS Method;
 wherein the means comprises an *acid-base treatment*.

In its opening brief, Par states that step (a) is the first step in its proposed “acid-base treatment.” *Supra*, 33 (identifying “dissolving crude free base with an organic solvent and adding an aqueous solution of tartaric acid to make the varenicline tartrate salt” as step (1) in the purported example “acid-base treatment” in Figure 1.) But the claim requires *both* steps (a) and (b). If step (a) is somehow part of step (b), then both steps are not present. A POSA would not understand whether the claimed “acid-base treatment” would include step (a)—“mixing varenicline free base with tartaric acid to form varenicline tartrate”—or if it requires a separate, additional, acid mixing step. Baertschi Declaration, JA374, ¶76. Claims 1, 12, 18, and 26 are indefinite because the claims fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *See Nautilus*, 572 U.S. at 901.

Moreover, if the court adopts Par’s construction or construes the term “acid-base treatment” substantially different from Zydus’s proposed construction, the term “acid-base treatment” would be indefinite for the following additional reasons.

Par’s proposed construction in the Joint Claim Construction Chart reads: “a process to separate a desired substance from an undesired substance via treatment with an acid and subsequent treatment with a base.” *Supra*, 30. In its Opening Position, Par proposes a narrowed construction, which requires forming and breaking a salt: “a process to separate a desired substance from an undesired one by treatment with an acid *to form a salt* followed by a subsequent treatment with a base *to break the salt*.” *Supra*, 30-31 (emphasis added).

Accordingly, even Par is struggling to clearly articulate the meaning of the phrase “acid-base treatment” based on the specification and the prosecution history. *See Nautilus*, 572 U.S. at 901 (A patent claim is invalid for indefiniteness if the claim, “read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”)

The goal of the definiteness requirement is to guard against the disadvantages that can arise from uncertain claim scope. *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 694–95 (Fed. Cir. 2019). “A patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them.’ Otherwise there would be ‘[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.’” *Nautilus*, 572 U.S. at 909-910 (internal citations omitted).

As discussed above, the ’524 patent is directed to synthesizing substantially pure varenicline and the ’524 patent specification does not define the term “treatment,” much less “acid base treatment.” The ’524 patent specification only describes one specific type of acid-base reaction. *See supra*, 32-35, ’524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 65:51-68:42 and Table 23. Although a POSA may understand that there are other types of acid-base reactions, there is no disclosure in the specification as to the metes and bounds of the “acid-base treatment” that would achieve a reduction in nitrosamine impurities to the claimed levels (e.g., less than 50 ppm). Baertschi Declaration, JA372-373, ¶¶73-74.

Par argues “[a] POSA would recognize that ‘acid-base treatment’ is broader than the specific liquid-liquid layer separation example described in the ’524 patent” and this “includes acid-base treatments that utilize a single solvent instead of two.” *Supra*, 34. But as explained

above, during the prosecution of the '524 patent, Par argued the opposite and emphasized the importance of using two solvents for layer separation. *See* '524 patent prosecution history, Mar. 29, 2023, Remarks at JA563, 14 (“This is a critical difference from the presently claimed invention, which first converts varenicline free base to water soluble varenicline salt ***and then*** removes the water insoluble nitrosamines by layer separation using an organic solvent. No layer separation of the nitrosamines is disclosed in Wei.”) (emphasis added in bold, italics in original). A POSA would not recognize what other forms of acid-base chemistry could specifically be used to achieve the claimed reduction in nitrosamine impurities, leaving a POSA with no certainty about the scope of the claims and rendering the claims indefinite. Baertschi Declaration, JA373, ¶74; *see e.g., PureChoice, Inc. v. Honeywell Int'l, Inc.*, 333 F. App'x 544, 548-549 (Fed. Cir. 2009) (finding claims indefinite based on a clear and unmistakable disavowal as to the claim term “environmental data.”).

### 3. Par's Reply Position

#### a. Zydus's Construction Conflicts with the Plain Meaning, the Specification, and Claims

Zydus's position has at least two flaws. First, Zydus argues that the “acid-base treatment” only requires an acid step, not a subsequent addition of base, because “the ‘subsequent treatment with a base’ merely returns the varenicline to its free base form.” *Supra*, III.D.2.c; Baertschi Decl., JA369-371 ¶¶ 62-66. To support this argument, Zydus cherry-picks statements from the specification to read the “base” out of “acid-base treatment.” Second, Zydus argues that the Court should limit the term to acid-base treatments that extract the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase. This argument imports limitations from the specification which are absent from the independent

claims and are differentiated from dependent claims which expressly require layer separation. The Court should reject Zydus's results-driven construction.

**(1) Zydus Fails to Rebut the Plain and Ordinary Meaning**

"Acid-base treatment" has a plain and ordinary meaning to POSAs. Dr. Dodds cited several examples to support his opinion where POSAs used the term consistent with Par's construction. Recognizing that the references Dr. Dodds cited are extrinsic, they provide an understanding of what the term means to a POSA, and it corroborates Par's proposed construction. *See, e.g.*, JA276 ("acid-base treatment i.e., salt making and breaking"). "Prior art references may be 'indicative of what all those skilled in the art generally believe a certain term means ... [and] can often help to demonstrate how a disputed term is used by those skilled in the art.'" *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999) (citation omitted).

Zydus, does not identify anything contradicting Par's proposed plain and ordinary meaning of the term "acid-base treatment." Rather, Zydus points to references regarding a specific type of acid-base treatment called an "acid-base extraction." But Zydus acknowledges that an "acid-base extraction" is a different and narrower term than the one being construed. *Supra*, III.D.2.a ("a POSA would know that there are other types of acid-base extractions.") Because Zydus does not establish that Par's proposed definition differs from the plain and ordinary meaning of the term "acid-base treatment," Zydus must meet the exacting standards to prove disclaimer, which it fails to do.

**(2) Zydus's Construction Conflicts with the Specification and Claims**

Zydus emphasizes that there is only one type of acid-base treatment mentioned explicitly in the '524 specification. However, Zydus ignores the blackletter law "expressly reject[ing] the contention that if a patent describes only a single embodiment, the claims of the patent must be

construed as being limited to that embodiment.” *Phillips*, 415 F.3d at 1323. Zydus cites *Verizon Servs. Corp. v. Vonage Holdings Corp.*, which did not limit the claim term based on a single described embodiment. Rather, the court found disclaimer based on descriptions of the claim limitation in the specification that were characterized as a feature of the invention as a whole. 503 F.3d 1295, 1308 (Fed. Cir. 2007). The opposite is true here where the examples and references to an acid-base treatment are all characterized as non-limiting examples. *See supra*, III.D.1.c(2).

Moreover, Zydus’s construction conflicts with the examples in the ’524 patent. In reading out the base step of an acid-base treatment, Zydus argues that the only step in the disclosed purification process that removes nitrosamine impurities is the addition of the acid and that the base step of the purification process merely returns the varenicline to its free base form. *Supra*, III.D.2.c; Baerschi Decl., JA369-370 ¶¶ 62-63. This ignores that each example of an acid-base treatment in the specification concludes with a basification step.

The acid-base treatment disclosed in the ’524 examples takes place in Stage-3 and purifies crude Varenicline Free Base. *See, e.g.*, ’524 patent, 13:16-25. The crude varenicline free base is treated with an acid to create a varenicline salt and then treated with a base to break the salt and return to purified varenicline free base. Dodds Rbt. Decl., JA538 ¶¶ 17-18. Indeed, the ’524 patent explicitly states that the acid-base treatment is not complete until the base step is performed: “Thereafter, pure free varenicline base can be isolated from the aqueous varenicline salt solution by basification (purification of varenicline by acid base treatment).” ’524 patent, 69:5-8.

Zydus’s position also conflicts with the claim language. As to the basification step, dependent claims, such as claims 6 and 20, require that ***the acid-base treatment*** include three

steps culminating with “(c) isolating purified varenicline free base *by adding a base* to the aqueous solution and extracting the purified varenicline free base with an organic solvent.”

Thus, Zydus’s contention that the basification cannot be considered part of an acid-base treatment because it “merely returns the varenicline to its free base form” (Baerschi Decl., JA370 ¶ 64; *supra*, III.D.2.c) is contradicted by the express language of the specification and claims.

Finally, Zydus’s efforts to rebut Par’s claim differentiation arguments fall flat. Zydus does not contest that its proposed construction would render superfluous the limitation “extracting the nitrosamine impurities with an organic solvent” in dependent claims 6 and 20. *Supra*, III.D.2.e. Zydus’s approach to dependent claim 13, which adds the term “layer separation,” fares no better. Zydus contends that its construction does not require layer separation which ignores that a POSA would recognize that the whole point of performing an acid-base treatment using two solvents, as required in Zydus’s construction, is to separate the two layers before performing the basification step. Dodds Rbt. Decl., JA539 ¶ 20.

#### **b. Prosecution History Disclaimer Does Not Apply**

Zydus argues that Par disclaimed claim scope during prosecution but has not met the heavy burden for applying the doctrine. The party invoking prosecution history disclaimer must prove the existence of a clear and unmistakable disclaimer that would have been evident to one skilled in the art. *See Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). The Federal Circuit has consistently declined to apply prosecution disclaimer where the alleged disavowal is ambiguous or amenable to multiple reasonable interpretations. *See id.* (citing cases). Finally, “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips*, 415 F.3d at 1317.

Here, Zydus ignores critical context and points to isolated statements from a March 29, 2023, amendment and response that rejected the then pending claims over WO2009027786 (“Ferrigone”) in view of WO20211259396 (“Wei”). In its response, Par amended the claims to include the acid-base limitation for the first time. *See* Dodds Rbt. Decl., Ex. F (3/29/2023 OAR) at JA551-556. Some of the claims, such as claim 1, were amended to generally include that the varenicline is obtained by acid-base treatment to remove N-nitroso-varenicline. Other claims explicitly provided the specificity that Zydus wishes to read into all the claims. For example, pending claim 16 recited that the acid-base treatment includes layer separation, basification, and extraction. Accordingly, if Par intended for its contemporaneous arguments to the examiner to suggest that “acid-base treatment” referred to something narrower, it would have done so explicitly in all the claims. Further, the examiner similarly did not view Par’s statements as constituting a disclaimer, as the examiner issued claims to an acid-base treatment broadly in addition to narrower ones limited to liquid-liquid extractions or layer separation. *See* ’524 patent, claims 1, 16, 22.<sup>10</sup>

With the claims amended to include an acid-base treatment, Par then traversed the rejections because none of the cited references, including Wei, “teach or suggest such acid-base treatment.” Dodds Rbt. Decl., Ex. F at JA558. Rather, Wei discloses a method called trituration that is performed by “beating” a solid material (in Wei, this is varenicline tartrate containing nitrosamine impurities) with a solvent intended to dissolve the impurity (nitrosamines) while leaving the desired substance (varenicline) in its solid form. *Id.* at JA560-562; Dodds Rbt. Decl., JA540-541 ¶¶ 22-24, JA566. Thus, although Wei teaches converting crude varenicline free base

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<sup>10</sup> Indeed, the MPEP § 608.01(m) instructs examiners to issue warnings or objections where claims cover the same thing, including when dependent claims do not specify a further limitation of the subject matter claimed.

to varenicline tartrate, a POSA would not consider this an acid-base treatment because Wei does not teach a basification step. The varenicline tartrate that is formed via acid addition in Wei remains in its salt form for the remainder of the process. A POSA would recognize the process taught by Wei to be fundamentally different than an acid-base treatment whether the acid-base treatment involves a liquid-liquid extraction with layer separation or another form of acid-base treatment such as one using a single solvent and precipitation.<sup>11</sup> Dodds Rbt. Decl., JA540-541 ¶¶ 23-24.

With this context, nothing in the March 28, 2023 response amounts to a clear and unmistakable disclaimer. Rather, the response reflects Par's effort to distinguish an acid-base treatment from trituration using the non-limiting example in the '524 patent as a guide. Indeed, Par provided a chart describing the exemplary acid-base treatment described in the '524 patent with supporting citations to the specification to illustrate the "general scheme of the acid-base treatment." Dodds Rbt. Decl., JA541 ¶ 25 (citing JA558). It is true that the cited example and figure employs an organic solvent and layer separation but, as Par made clear in the sentence just following, the example was provided to illustrate the general scheme of an acid-base treatment. A POSA would not view these statements, and the additional statements cited by Zydus from the table illustrating the general scheme of an acid-base treatment, to constitute a clear and unmistakable disclaimer of claim scope. Dodds Rbt. Decl., JA542 ¶ 27.

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<sup>11</sup> Par's construction of "acid-base treatment," which would encompass treatments that use a single solvent and precipitation, does not conflict with how Par distinguished Wei. Although Wei discusses the beating/trituration purification process reducing impurities by "solid-liquid separation," that is very different than an acid-base treatment because the solid-liquid separation disclosed in Wei is washing/beating the varenicline tartrate salt form and does not involve any subsequent basification step. See Dodds Rbt. Decl., Ex. G (Wei) at JA593; Dodds Rbt. Decl., JA544 ¶ 30.

Zydus points to additional statements from the prosecution addressing what Wei did not teach, but these also fail to demonstrate disclaimer. *Supra*, III.D.2.b; Dodds Rbt. Decl., JA542-543 ¶ 28. For example, Zydus points to Par's statement that "Wei does not teach the claimed acid-base treatment, *i.e.*, Wei does not teach that an acid can be used to perform a layer separation wherein the aqueous layer would contain a substantially pure varenicline tartrate product and the organic layer would contain the water insoluble nitrosamine impurities." *See supra*, III.B.2. The statement is true; however, it does not amount to a clear and unmistakable disclaimer of other types of acid-base treatments that are encompassed by the term. A POSA would understand the plain meaning of "acid-base treatment" to involve a treatment with an acid to form a salt and subsequent treatment with a base to break the salt. Dodds Rbt. Decl., JA537 ¶ 15. A POSA would readily understand that Wei's disclosure of trituration is not an acid-base treatment, and view Par's statements as distinguishing Wei's trituration method from an acid-base treatment using the example in the '524 patent as a guide. JA540-544 ¶¶ 23-30.

Zydus further argues that Par emphasized the importance of aqueous/organic layer separation during prosecution, pointing to Par's statement that "[t]his is a critical difference from the presently claimed invention, which first converts varenicline free base to water soluble varenicline salt and then removes the water insoluble nitrosamines by layer separation using an organic solvent." *Supra*, III.D.2.b (citing JA563). Context again is important, and in the sentence immediately prior, Par pointed out that there is no disclosure in Wei of nitrosamine impurities being removed before the "slurry wash/beating treatment." JA562-563. Par's statement referred to the lack of an acid-base treatment in Wei and did not, narrow the scope of the term "acid-base treatment" in the claims. A POSA would conclude that the discussion provided an example of how Wei's trituration method differs from an "acid-base treatment."

Dodds Rbt. Decl., JA543-544 ¶ 29. The patentee did not disclaim the common usage of the term.

Zydus misapplies the case law on the disclaimer doctrine. Arguments during prosecution to distinguish prior art are not enough to establish disclaimer without a clear and unequivocal surrender of claim scope. For example, in *K-fee System GmbH v Nespresso USA, Inc.*, the parties disputed the construction of the term “barcode.” Defendant pointed to prosecution statements that distinguished the claimed “barcodes” from a prior art reference that disclosed “bit codes” that can encode two states corresponding to 0 and 1. 89 F.4th 915, at 921 (Fed. Cir. 2023). During prosecution, Plaintiff argued that unlike a bit code, barcodes have variable width bars and therefore contain more than only binary symbols of 0 and 1. *Id.* Based on these statements, the district court construed “barcodes” to exclude codes corresponding to only 0s and 1s. *Id.* The Federal Circuit reversed, finding the court’s construction too restrictive given the lack of any statement clearly and unambiguously disclaiming all bit codes from the meaning of barcode. *Id.* at 923-24. Accordingly, the Federal Circuit concluded that the “only thing K-fee clearly distinguished before the EPO was [the prior art reference] itself.” *Id.*, at 924.

The same is true here. Par distinguished Wei from an acid-base treatment. However, that distinction fails to provide a clear and unmistakable disclaimer of acid-base treatments other than those involving extractions and layer separation. Even if the statements cited by Zydus were somewhat ambiguous, which they are not, that is insufficient to establish disclaimer. *See Mass. Inst. of Tech.*, 839 F.3d at 1119.

Zydus’s cited cases are inapposite or support Par’s construction.<sup>12</sup> For instance, in *Grober v. Mako Products, Inc.*, the district court narrowly construed “payload platform” based

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<sup>12</sup> Zydus’s citations to *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 993-94

upon purported disclaimers during prosecution. 686 F.3d 1335, 1341 (Fed. Cir. 2012). The Federal Circuit, noting the ambiguities often created during prosecution, *reversed* the district court, holding that “Grober’s statements in reference to the prior art did not narrow the meaning of the patent” and that the statements were not an unambiguous disavowal that clearly and unmistakably disclaimed claim scope or meaning. *Id.* at 1342-43. Again, merely distinguishing prior art was insufficient.

**c. Zydus’s Invalidity Arguments Are Misplaced**

Zydus posits, via unsupported attorney argument, that the claims would be invalid for lack of written description and enablement if the Court rejects its construction. *Supra*, III.D.2.d. Zydus must prove invalidity for lack of written description and enablement, which are factually intensive inquiries from the perspective of a POSA, by clear and convincing evidence. *See Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1368-69 (Fed. Cir. 2014). Par disagrees, and Zydus’s unsupported argument does not come close to meeting its burden. Claim construction is not the time to address written description and enablement.

**d. Zydus’s Indefiniteness Argument Fails**

Zydus contends that if the Court rejects its construction, then the claims are indefinite. But Zydus cannot meet its clear and convincing burden.

To start, Zydus’s expert Dr. Baertschi bases his indefiniteness conclusion on his opinion that the term “acid-base treatment” is not well-understood in the art. However, Dr. Dodds disagrees, and unlike Dr. Baertschi, Dr. Dodds supported his opinion as to the plain and ordinary

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(Fed. Cir. 2003) and *AccuScan, Inc. v. Xerox Corp.*, 76 F. App’x 290 (Fed. Cir. 2003) are inapposite because they involved situations where the patentee attempted to recapture through claim construction the very thing that the patentee distinguished to overcome prior art. Here, Par does not attempt to recapture the purification method taught in Wei.

meaning of the term “acid-base treatment” with other examples of POSAs in the field using the same term the same way. JA197-201, Exs. D-F (JA245-343); Dodds Rbt. Decl., JA545 ¶ 34. This alone precludes a finding of indefiniteness at the claim construction stage. Zydus then contends that if the Court rejects its construction, a POSA would not know what other acid-base treatments “would achieve a reduction in nitrosamine impurities to the claimed levels.” *Supra*, III.D.2.f. This, however, confuses the definiteness requirement with enablement, which is a mixed question of fact and law and unrelated to the claim construction process.

Finally, Zydus contends that the claims are indefinite because the claims require a step of “mixing varenicline free base with tartaric acid” and an “acid base treatment.” According to Zydus, since the acid-base treatment can include the addition of tartaric acid to varenicline free base, both the mixing and acid-base steps can occur in a single step. From here, Zydus makes the illogical and legally unsupported conclusion that “[i]f step (a) is somehow part of step (b), then both steps are not present.” First, there is no reason why a single action could not satisfy multiple limitations in a method claim, and Zydus cites no authority for its position. Second, and critically, Zydus’s argument is premised on its incorrect position that merely adding an acid can constitute an acid-base treatment.

The ’524 patent example describes four general steps to making substantially pure varenicline tartrate API: (1) Preparation of the diamino intermediate (Stage-1); (2) preparation of the quinoxaline intermediate (Stage-2); (3) preparation of purified varenicline free base (Stage-3); and (4) then using that purified varenicline free base to make a varenicline tartrate maltodextrin premix (Stage-4). *See, e.g.*, ’524 patent, 7:13-29, 12:60-17:17. The acid-base treatment takes place in stage three and the acid used can be tartaric acid or others such as fumaric, succinic, or citric acid. *See, e.g.*, ’524 patent, 68:18-67 (Table 23). The acid-base

treatment concludes with a basification step to obtain pure varenicline free base. Then in the final stage (stage 4) the purified varenicline free base is mixed with tartaric acid to make purified varenicline tartrate.

Accordingly, a POSA would have no trouble understanding the scope of the claims. The acid-base treatment occurs when varenicline free base is combined with an acid to form a salt, followed by a basification step to obtain purified varenicline free base. Then, the purified varenicline free base is mixed with tartaric acid to make the active varenicline tartrate pharmaceutical substance. Accordingly, regardless of whether tartaric acid is used at the acid treatment step of the acid-base treatment or only after the acid-base treatment has been completed to yield pure varenicline free base, a POSA would know the scope of the claims and when each step is performed. Dodds Rbt. Decl., JA546 ¶ 36.

#### **4. Zydus's Sur-Reply Position**

##### **a. There is no “plain and ordinary meaning” of this term**

Par's only support for its “plain and ordinary meaning” is extrinsic expert testimony citing a grand total of three extrinsic references: two patent applications with different inventors who could act as their own lexicographers, and one article that does not even use the term “acid-base treatment.” Baertschi Resp., JA614-616, ¶¶4-6. The Federal Circuit has rejected this type of evidence to establish “plain and ordinary meaning.” *See, e.g., Sequoia Tech., LLC v. Dell, Inc.*, 66 F.4th 1317, 1324 (Fed. Cir. 2023) (rejecting patentee's reliance on thirty-four patents and patent applications to establish “plain an ordinary meaning”, reasoning “[t]hat other inventors chose to be their own lexicographers and define [the term] does not demonstrate what [the term] means in the context of the [patent-in-suit]. Nor does it establish the plain and ordinary meaning of [the term].”). Par is incorrect that Zydus has not “identif[ied] anything contradicting Par's proposed plain and ordinary meaning of the term.” *Supra*, 52. Zydus's

expert explained that “acid-base treatment” is not a term commonly understood by a POSA. Baertschi Resp., JA614, ¶3. That Zydus and its expert do not cite literature (or patent applications) proving this negative is unremarkable and underscores that it is not a commonly used term.

Par’s expert’s declaration is not only unsupported; it is also at odds with the intrinsic evidence. *Phillips*, 415 F.3d at 1318 (“[A] court should discount any expert testimony ‘that is clearly at odds with the claim construction mandated by ... the written record of the patent.’”); *see supra*, 40-42. Here, the purpose of the claimed “acid-base treatment” is to reduce nitrosamine impurities. This purpose “informs the proper construction of claim terms.” *Kaken Pharm. Co. v. Iancu*, 952 F.3d 1346, 1352 (Fed. Cir. 2020). The specification describes only one “acid-base treatment” that achieves this purpose:

[b]ecause the absence of basic nitrogen due to the presence of the nitroso group prevents the nitrosamine impurities to form salt of acids, ***nitrosamine impurity fails to dissolve in the aqueous solution, and could be extracted in an organic solvent.*** Thus, nitrosamine impurities could be completely removed in ***this*** acid-base treatment process.

*Supra*, 41; ’524 patent, 22:19-30. Neither this section nor the section relied on by Par (’524 patent, 13:16-25) require a subsequent treatment with a base. And the disclosure that varenicline free base *can* be isolated by basification *after* the purification step (*supra*, 53, citing ’524 patent, 69:5-8) is hardly a basis to *require* basification as part of the “acid-base treatment.”

Regarding dependent claims 6 and 20, Par takes contradictory positions. In its opening position, Par argues that the addition of a limitation in a dependent claim creates a presumption that it is not also present in the independent claim. *Supra*, 38-40. Par argues in its reply position that the “acid-base treatment” in the independent claim requires basification because it is required in dependent claims. *Supra*, 53-54. Par cannot have it both ways. Par also mischaracterizes Zydus’s position. Zydus does not contend “the basification ***cannot be***

*considered* part of an acid-base treatment;” just that the “acid-base treatment” in the dependent claims adds additional steps that are not required in the independent claims. *Supra*, 54(emphasis added), *compare to* 43.

**b. Par disclaimed any broader scope of “acid-base treatment”**

Par’s statements during prosecution constitute a clear and unmistakable disclaimer of any broader claim scope. *See supra*, 42-43. To overcome obviousness, Par amended its claims to require “acid-base treatment” and characterized its “invention” as a process requiring the “acid-base treatment” described in the specification:

- “Wei does not teach *the claimed acid-base treatment, i.e.*, Wei does not teach that an acid can be used to perform a *layer separation* wherein the *aqueous layer* would contain a substantially pure varenicline tartrate product and the *organic layer* would contain the water insoluble nitrosamine impurities;”
- “As detailed in Figures 1, 11 and Table 3 of Applicant's specification, *the* acid-base treatment employs an organic solvent and *layer separation* to remove the water insoluble nitrosamine impurities;”
- “This is a *critical* difference from the *presently claimed invention*, which first converts varenicline free base to water soluble varenicline salt and then removes the water insoluble nitrosamines by *layer separation* using an organic solvent.”

*Id.* This is disclaimer, because Par relied on liquid-liquid “layer separation” (“a critical difference”) to overcome the prior art rejection. *See Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1358 (Fed. Cir. 2017) (affirming prosecution disclaimer because “[t]he patentee’s disclaimer may not have been necessary, but its statements made to overcome [the prior art] were clear and unmistakable.”); *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1363 (Fed. Cir. 2017) (holding that patentee’s statement that a feature “is a key aspect of its invention” can be considered as a clear and unmistakable disclaimer).

These statements refer broadly to “the claimed acid-base treatment” or “the presently claimed invention,” and are not limited to dependent claims. Par’s reply argues that the

patentees distinguished Wei simply because Wei did not teach an acid-base treatment generally. *Supra*, 55. But that is not what the patentees said. Par’s reliance on “context” ignores the patentees’ statements describing their invention. *See Tech. Props.*, 849 F.3d at 1358.

Moreover, that the examiner issued claims having different scope does not overcome Par’s disclaimer, since disclaimer often results in independent claims requiring limitations recited in dependent claims. *Biogen*, 713 F.3d at 1097 (rejecting argument that dependent claims support a broader construction of the independent claim because prosecution history disclaimer overcomes claim differentiation).

Even if Par’s statements during prosecution somehow did not establish disclaimer, they would still support Zydus’s construction, because they reinforce the disclosures in the specification regarding “acid-base treatment.” *Ajinomoto Co. v. Int’l Trade Comm’n*, 932 F.3d 1342, 1349 (Fed. Cir. 2019) (“Because the prosecution history reinforces what is already suggested by the claim language and specification, this case provides no occasion, contrary to [patentee’s] contention, for requiring clear and unmistakable disavowal or disclaimer to justify a claim construction.”).

**c. Par’s proposed construction would render the claims invalid for lack of written description and enablement**

Zydus is not attempting to prove lack of written description and enablement at this stage. Zydus is merely raising invalidity issues that come with Par’s proposed construction as another reason that the court should reject that construction. *Phillips*, 415 F.3d at 1327 (courts should construe claims to preserve validity, where possible); *see also MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012) (The enablement “doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt

to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.”).

**d. The claims are indefinite under Par’s construction**

Courts can and do address indefiniteness at the claim construction phase of the case. *f’real Foods, LLC v. Hamilton Beach Brands, Inc.*, 388 F. Supp. 3d 362, 364 (D. Del. 2019), *aff’d*, 854 F. App’x 379 (Fed. Cir. 2021).

Par and Dr. Dodds contend that “other POSAs” use the term “acid-base treatment.” Resp. Dodds Decl., JA537, ¶ 15. Dr. Dodds’s use of this term “with other POSAs” is purely anecdotal, and not a basis to ascribe a “plain and ordinary meaning” to the term. *XMTT, Inc. v. Intel Corp.*, 657 F. Supp. 3d 591, 601 (D. Del. 2023) (“conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court”). Dr. Dodds provides no evidence that these “other POSAs” qualify as POSAs here. And although Par and Dr. Dodds describe purported examples of “acid-base treatments” beyond the type of reaction disclosed in the specification and prosecution history, they provide no evidence that those examples, much less any other “acid-base treatments,” would reduce or remove nitrosamine impurities. Par’s attempt to re-characterize this as enablement ignores that a claim is indefinite if a POSA reading the claim would not reasonably be able to ascertain the scope of the claims.

Par’s response to Zydus’s other indefiniteness argument assumes that basification is required in “acid-base treatment.” *Supra*, 60-61; Baertschi Resp., JA619, ¶13. But the specification is clear that it is not. ’524 patent, 22:19-30 (describing converting varenicline base into the varenicline salt and extracting nitrosamine impurities in an organic solvent as the “acid-base treatment”). Par also claims that “there is no reason why a single action could not satisfy multiple limitations in a method claim,” but cites no authority. In fact, where multiple steps are required, all of those steps must be performed. *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1029

(Fed. Cir. 2019) (finding that the accused infringer's one-step process does not infringe because the claim language, by enumerating steps, logically requires the process steps be performed separately.).

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